UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO:	)	
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., No. 07-CV-11618-PBS	)	Hon. Patti B. Saris

ABBOTT LABORATORIES INC.'S RESPONSE TO PLAINTIFF'S LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS

Pursuant to Local Rule 56.1, Abbott Laboratories Inc. ("Abbott"), responds to Ven-A-Care's Statement of Undisputed Facts states as follows:

1. Abbott Corporation at all times from 1991 until the present operated a division it called the Pharmaceutical Products Division ("Abbott PPD"). (Complaint ¶16) (Answer ¶16)

RESPONSE: Disputed. There is no entity known as Abbott Corporation. Abbott admits that during the period alleged in the Complaint (1994-2007) Abbott Laboratories had a division known as the Pharmaceutical Products Division ("PPD").

2. PPD sold all of the Erythromycin drug products (Erys) that are at issue in this lawsuit. These products are sold under 43 different NDCs depending upon packaging size, type and volume. These products are used to treat different types of infections. (Complaint ¶49, n.3)

RESPONSE: Abbott admits that its PPD sold Ery drug products listed in paragraph 33 of the Complaint, comprising 17 Ery formulations, and that the Erys were prescribed to treat infections but certain Ery formulations were also used to treat other conditions. Abbott denies any other statement in this paragraph.

3. While technically brand "innovator" drugs, all of these Ery products were sold by Abbott as "multi-source," generic drug products, which could be acquired from any number of competing pharmaceutical manufacturers, including Abbott. (Complaint ¶51) Beth Garvin-

Senger Tr. 12/17/08 at 15:15-16:21. (Declaration of Susan Schneider Thomas in Support of Motion for Summary Judgment, hereinafter Thomas Exhibit 1.)

RESPONSE: Undisputed with respect to the relevant claims period.

4. Most other PPD products, however, were sold as brand name drug products. Joseph Fiske Tr. 2/18/09 at 321:5 to 321:10. (Thomas Exhibit 2)

RESPONSE: Undisputed.

5. All of the named Ery products were generally eligible for reimbursement under Medicaid, since Abbott has a rebate agreement with CMS.

RESPONSE: Undisputed.

6. In the 1990's, Abbott's PPD reported AWPs for its products to the pricing compendia. See Kristen Minne Tr. 11/18/08 at 206:5-207:16, 227:9-228:13, 229:5-231:10 (Thomas Exhibit 46); Kristen Minne 11/18/08 Tr. Exhibit 22 (Thomas Exhibit 47), Minne Exhibit 26 (Thomas Exhibit 48), Minne Exhibit 27 (Thomas Exhibit 49), Minne Exhibit 29 (Thomas Exhibit 50), and Minne Exhibit 31 (Thomas Exhibit 51). Thereafter, for all products sold by PPD, Abbott understood the published AWP was derived by the pricing compendia from Abbott's reported list price or WAC. For most products sold by PPD, Abbott reported a list price that was 5% above the actual wholesale cost paid (WAC) for the drugs. This was the practice since before 1991. Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibits 33 (Thomas Exhibit 3) and Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibit 34 (Thomas Exhibit 4). Abbott's corporate representative for PPD pricing issues testified that PPD used WAC as the price that a wholesaler generally pays for a product, the invoice price for the product, for most PPD products. Joseph Fiske Tr. 2/18/09 at 316-317 (Thomas Exhibit 2); *see also* Debra DeYoung Tr. 3/20/07 at 203-204 (Thomas Exhibit 5). It was only when Mr. Fiske was trying to explain why Abbott reported WACs that were *not* the prices at which wholesalers were invoiced for the Erys that he tried to draw a distinction between a "published wholesale acquisition cost" as compared to "what the wholesaler paid for the product, … the base deal price." Joseph Fiske Tr. 3/22/07 at 518-519 (Thomas Exhibit 55).

RESPONSE: Abbott objects to paragraph 6 because "Abbott" is not defined for the purposes of determining what constitutes corporate knowledge, including what "Abbott understood." Abbott further objects to paragraph 6 to the extent it defines WAC as "actual wholesale cost paid." Several sources, including the federal government, define WAC as an undiscounted list price. (*See*, Minne 92, Red Book definition of WAC: the "manufacturer quoted list price to wholesale distributors, and does not with any deal terms or specialized contract pricing," Ex. 166; 42 U.S.C. § 1395w-3a(c)(6)(B) ("The term 'wholesale acquisition cost' means, with respect to a

drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price"), Ex. 15.)

Subject to and without waiving the objection, Abbott disputes the statement. Abbott states that, at certain times until 2001, Abbott PPD reported an *estimated* AWP for its products. (30(b)(6) Fiske Dep. at 119:19-120:11, Ex. 2.) Abbott PPD made clear that it was not setting AWPs on its products. (*See* Gerzel Ex. 10 ("Abbott does not control how Red Book does its business nor does Abbott provide AWP or a calculated markup to establish an AWP. Consequently, Abbott concluded that there was no need to respond to Ms. Voeck's April 2003 letter. Abbott trusts that Red Book will continue to conduct its business as it sees fit."), Ex. 23.) (*See also*, 2/20/09 Gerzel Dep. at 127:5-129:14, Ex. 10; 30(b)(6) Fiske Dep. at 142:18-144:12, Ex. 2.) Abbott further states that the record establishes that numerous Abbott PPD employees were not aware of the relationship between any price that Abbott PPD reported and the AWPs set by compendia. (1/15/09 Lehn Dep. at 40:23-41:2, Ex. 3; 2/19/09 Parker Dep. at 58:16-59:9; 87:21-88:2, Ex. 6; 2/20/09 Gerzel Dep. at 54:9-16, Ex. 10.) Abbott denies Paragraph 6 because it misrepresents the testimony of Mr. Fiske. Mr. Fiske testified that PPD considered WAC as its "non-discounted price to the wholesaler." (30(b)(6) Fiske Dep. at 112:8-13, Ex 2.) Abbott PPD, in accordance with its understanding of what information it was instructed to report to the compendia, reported its WAC prices. (*Id*. at 166:24-167:7.) Abbott states that it established WAC as its undiscounted price to wholesalers without any contracts or terms. (*Id*. at 198:13; 12/7/08 Senger Dep. at 34:17-21, Ex. 5.) Abbott PPD calculated the WAC price as 95% of its list price. (30(b)(6) Fiske Dep. at 112:19-23, Ex. 2.)

7. For some generic products sold by PPD, including the Ery products, Abbott deviated from its normal PPD business practice and reported prices to the pricing compendia that

bore no reliable relationship to the actual prices at which wholesalers or others bought its drugs. Instead of reporting actual wholesaler invoice prices for the Erys, known as Base Deal prices, PPD concealed these Base Deal prices and reported inflated WACs. The practice of reporting WACs that were not the prices at which wholesalers were invoiced for Ery products began before 1993 and continued until at least July 2003. Joseph Fiske Tr. 2/18/09 at 318-319 (Thomas Exhibit 2).

RESPONSE: Disputed. Paragraph 7 misrepresents Joe Fiske's testimony. Abbott reported its List Price and its WAC prices for Ery, as well as its other PPD drugs. (2/19/09 Parker Dep. at 55:20-56:7, Ex. 6; 30(b)(6) Fiske Dep. at 158:5-16, Ex. 2.) List Price was the price available to customers who did not have a contract with Abbott and who were purchasing less than a case of Ery. (1/15/09 Lehn Dep. at 100:14:14-22, Ex. 3.) Customers purchasing a case or more of Ery, but less than $500 of Ery, paid WAC. (12/7/08 Senger Dep. at 34:17-21, Ex. 5.) Both List Prices and WACs were actual prices paid by customers in the marketplace. (Lehn Dep. at 215:8-10, Ex. 3; 12/7/08 Senger Dep. at 173:18-174:8 ("If somebody came to us directly and wanted to buy a case, they would pay us WAC."), Ex. 5; Young Aff., Ex. 7 ¶ 3.) Abbott admits that until July 2003 it offered terms – a minimum of $500 of Ery product on a single invoice – for wholesalers to purchase Ery at a discounted price, known as Base Deal Price. (30(b)(6) Fiske Dep. at 71:8-20, Ex. 2.) Abbott further states that those customers that did not meet the terms for Base Deal Price paid WAC. (*Id*. at 206:21-19, Ex. 2; Pavlik Dep. at 35:2-36:1, Ex. 1.) Abbott disputes the contention that Abbott PPD was deviating from its normal business practice by offering these Base Deal Prices. Ven-A-Care's statement is a red herring. Abbott PPD offered discounted prices on the Erys when Abbott needed to offer lower prices to compete with generic manufacturers entering the market after Abbott's Erys lost patent protection. (30(b)(6) Fiske Dep. at 45:17-46:3; 363:2-22, Ex. 2.) There is no similar need to offer discounted prices on branded products. Abbott disputes the statement that PPD "concealed" its Base Deal Prices. Abbott's sales at Base Deal Prices were reflected in the Average Manufacturer Prices ("AMPs")

it reported directly to the U.S. government. (*Id*. at 188:3-189:11;12/7/08 Senger Dep. at 117:3-8, Ex. 5.) Abbott admits that it discontinued the use of Base Deal Price in July 2003. (30(b)(6) Fiske Dep. at 50:12-25, Ex. 2.)

8. Market prices for the Ery drugs were not reported and were considered to be confidential. Beth Garvin-Senger Tr. 12/17/08 at 26:5 to 26:13 (Thomas Exhibit 1). No disclosure was made to Medicaid that the Ery products had invoice prices to wholesalers that were lower than published WACs (which were normally the invoice prices for PPD drugs). Beth Garvin-Senger Tr. 12/17/08 at 213:6 to 213:15 (Thomas Exhibit 1); Joseph Fiske Tr. 2/18/09 at 371:18 to 371:19 (Thomas Exhibit 2) (Abbott did not report a price lower than the inflated WAC price to the pricing compendia); Joseph Fiske Tr. 3/22/07 at 457:3 to 457:8 (Thomas Exhibit 13) (Abbott did not report base deal prices to pricing compendia); Joseph Fiske Tr. 3/22/07 at 516-517 (Thomas Exhibit 55) (catalogs and price lists that were sent to wholesalers with list and base deal prices were not sent to pricing compendia); Debra DeYoung Tr. 3/20/07 at 270:20 to 270:21 (Thomas Exhibit 5) ("PPD never submitted contract pricing to First DataBank").

RESPONSE: Disputed. The List Prices and WACs were in fact market prices, set for legitimate business reasons and paid by customers, and were reported appropriately. (Young Aff., Ex. 7 ¶ 3; 1/15/09 Lehn Dep. at 100:14:14-22 (When stores "ran out of a product and needed to get it before they were reimbursed by their own distribution centers, they purchased at list."), Ex. 3; *id*. at 215:8-10; 12/7/08 Senger Dep. at 173:18-174:8 ("If somebody came to use directly and wanted to buy a case, they would pay us WAC."), Ex. 5.)

Abbott does not dispute that it treated the contracts and terms for discounted prices as confidential. (30(b)(6) Fiske Dep. at 116:14-117:8, Ex. 2.) Abbott disputes Ven-A-Care's statement that "[n]o disclosure was made to Medicaid [. . .]." Abbott PPD reported AMPs which, by statute, were calculated to reflect an average of market prices. (30(b)(6) Fiske Dep. at 188:3-189:11, Ex. 2; 12/7/08 Senger Dep. at 117:3-8, Ex. 5.) Moreover, the government received numerous reports showing that the AWPs were higher than the average actual acquisition costs for generic drugs generally and for the Erys specifically. (SOAF at ¶¶ 58-59, 62-68, 71-79.) The U.S. government recognized the confidential nature of Abbott's discounted pricing on contract or terms, so much so that the government refused to share the AMP data with

the states even though it was permitted to. (9/26/07 Reed Dep. at 271:13-19; 355:18 -356:8, Ex. 167.)

9. There was no set or predictable relationship between the published prices for Ery drugs and the actual contract prices at which those drugs were sold. Beth Garvin-Senger Tr. 12/17/08 at 28:1 to 28:11 (Thomas Exhibit 1). Joseph Fiske Tr. 3/22/07 Exhibit 536 (Thomas Exhibit 9).

RESPONSE: Disputed and, to the extent not disputed, immaterial. Abbott set contract prices discounted from the List Prices and WACs based on legitimate and independent business reasons. (SOAF at ¶ 1-4) In order to compete with manufacturers of generic forms of Ery, Abbott offered its customers terms and contracts for the Erys. (*Id.* at ¶ 3.) Pursuant to these agreements, customers were given discounts and rebates in exchange for purchasing certain amounts and shares of requirements from Abbott, for providing sales data, and for other considerations. (*Id.*) Abbott's contract prices were set at a level to allow Abbott to compete with, but not necessarily beat, the prices offered by the competitor generic manufacturers. (*Id.* at ¶ 4.) Abbott objects to, as immaterial, any suggestion that there was supposed to be, by law or otherwise, a consistent, set, predictable mathematical relationship between the published List Prices and WACs on the one hand and lower contract prices on the other hand. Furthermore, Ven-A-Care's citations do not support the statement asserted. Ms. Senger's testimony did not concern or in any way refer to Ery but focused only on Depakote. (12/7/08 Senger Dep. at 28:1-11, Ex. 5.) Nor does Thomas Exhibit 9, provide support for the statement.

10. The Abbott employees responsible for reporting prices to the pricing compendia for PPD drugs, including the Ery products, had access to the bid schedule pricing that was used to invoice wholesalers. Joseph Fiske Tr. 2/18/09 at 361:6 to 361:10 (Thomas Exhibit 2).

RESPONSE: Disputed as unsupported and immaterial. The cited Fiske deposition does not even remotely support the statement. Moreover, the statement is immaterial because it

erroneously assumes that bid schedule pricing was relevant to Abbott PPD's reporting obligations (which in fact there was none).

11. Abbott, as a corporation, had another pharmaceutical division known as the Hospital Products Division ("HPD"). Abbott's HPD did not follow the same general practice as PPD. HPD reported a list price that was increased almost every year and that bore no relationship to the declining market prices for the products. This HPD practice was similar to PPD's unique Ery practice. In 2001, however, Abbott HPD implemented new pricing policies, which required list price to be set at 5% above its real average wholesale price. (Draft – Catalog Price Adjustment – "The wide disparity in catalog prices and average market prices as currently configured is not supported by sufficient financial or market factors to survive scrutiny of public opinion.") (Abbott Exhibit 940 (Thomas Exhibit 87)) This is the same policy Abbott's Pharmaceutical Products Division had maintained since before 1991 except for Ery and some other multi-source products. Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibits 33 (Thomas Exhibit 3) and Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibit 34 (Thomas Exhibit 4). The change in HPD price reporting practices was, at least in part, the result of a government investigation into Abbott's price reporting conduct. Joseph Fiske Tr. 3/22/07 at 463:7 to 463:24 (Thomas Exhibit 55).

RESPONSE: Disputed. Abbott PPD did not raise Erys' List Prices and WACs every year, the List Prices and WACs were "market prices" (*see* SOAF ¶ 17); and the Erys' contract prices increased, not declined during the Complaint period. (1/22/09 Pavlik Dep. at 155:20-156:5 (increases in contract prices in 2005), Ex. 1; 12/17/08 Senger Dep. at 124:13-125:9, Ex. 5.) In fact, Abbott PPD raised the Erys' List Prices and WACs only five times during the fourteen-year period alleged in the Complaint, and these were only modest increases to keep pace with inflation. (30(b)(6) Fiske Dep. at 47:10-23, Ex. 2; Young Aff., Ex. 7 ¶ 4.) Abbott further disputes that PPD's "business practices" with respect to Ery were similar to HPD's, but any comparison is immaterial. Moreover, Ven-A-Care should be estopped from using such evidence in this case; it opposed a motion to dismiss that was based on the FCA's first-to-file bar by arguing that this case about Erys is totally difference than the case about the HPD products. In this paragraph and in all others, mentioning HPD, Abbott disputes the statements to the extent they were disputed in Abbott Laboratories Inc.'s Response to the Amended Statement of Undisputed Facts in Support of United States' Memorandum of Law in Support of Cross-Motion

for Partial Summary Judgment and in Opposition to Abbott Laboratories Inc.'s Motion for Summary Judgment, which are incorporated herein.

Subject to and without waiving its objections, Abbott states that its policy has always been to establish WAC price at 95% of list price. (30(b)(6) Fiske Dep. at 112:9-13, Ex. 2.) Abbott further states that due to competitive forces, Abbott and other manufacturers offered customers discounts on the prices of multisource drugs. (SOAF ¶ 3, 17.) Abbott had legitimate business reasons for maintaining its List Prices and WACs on the Erys. Abbott has significant, high-profit sales at the List Prices and WACs. (1/15/09 Lehn Dep. at 110:17-21, Ex. 3.) In addition, the List Prices and WACs gave customers the incentive to contract with Abbott. List Price and WAC served as a starting price point under which various tiers of discounted contract prices were offered. (12/17/08 Senger Dep. at 162:8-14; 180:11-17, Ex. 5.) Abbott disputes the premise that contract prices were declining. (SOAF ¶ 17.)

12. Joe Fiske, Abbott's corporate representative regarding PPD pricing, could not explain why the lower prices at which wholesalers were invoiced for Ery products were not the WAC prices that were reported to the pricing compendia, other than to say that the pricing compendia expected WAC and list pricing from manufacturers. Joseph Fiske Tr. 2/18/09 at 322:12 to 322:23 (Thomas Exhibit 2). The decision not to change the Ery product prices in 2001 with the HPD price changes was discussed in an agenda termed "Rules of the Road" prepared in connection with the HPD price changes. Mr. Mike Sellers, General Manager, Contract Marketing, wrote: "Per directions from last meeting: 1. Discussed price adjustment with other Divisions: PPD – Standard WAC prices at 5% below List; *potential exposure on Ery products which are sold at 40% to 60% below List*; some sales volume risk with low List price." (emphasis added). Michael Sellers 30(b)(6) Tr. 3/31/08 Exhibit 33 (Thomas Exhibit 3); Joseph Fiske Tr. 2/17/09 Exhibit 13/Michael Sellers Tr. 4/12/07 Exhibit 590 (Thomas Exhibit 93). Sellers testified that the concern about sales volume risk was expressed by Joe Fiske. Michael Sellers 30(b)(6) 3/16/08 Tr. at 312:3 to 312:22 (Thomas Exhibit 88). Despite this perceived exposure from leaving the reported prices for the Ery products unchanged, that is precisely the path that Abbott chose.

RESPONSE: Disputed. Mr. Fiske did in fact explain why Abbott was reporting List Prices and WACs to the compendia. (30(b)(6) Fiske Dep. at 166:24-167:7; 195:7-14; 197:2-6, Ex. 2.) Ven-A-Care misrepresents Thomas Ex. 3 and has no support for its interpretation of the document.

Subject to and without waiving its objections, Abbott states that its decision to change the list prices for Ery drugs was motivated by a desire to remain competitive at the list price level. (3/16/08 Sellers Dep. at 244:8-21, Ex. 168.) Mr. Sellers testified that price adjustments for Ery products were discussed in 2001 because in order to remain competitive with other generic manufacturers that had entered the marketplace, discounted contract prices had been offered, but there had yet not been a corresponding change to list price. (*Id*. at 244:8-21.) Mr. Sellers further explained the concern regarding sales volume risk as follows: "[w]hen you reduce your list price, any sales that you would have anticipated making at a noncontract sales are going to come in at a lower price than what you would have historically seen." (*Id*. at 245:20-246:7.) In addition, wholesalers were invoiced at WAC when they purchased Ery pharmaceuticals at WAC. (30(b)(6) Fiske Dep. at 87:6-11, Ex. 2.) Abbott disputes Ven-A-Care's erroneous and unsupported assumption that PPD affirmatively decided not to lower List Prices and WACs in 2001. Any comparison to or discussion of HPD is immaterial. (*See* RSOF ¶ 11.)

13. When Abbott provided information on a new drug product to Texas Vendor Drug Program, it identified whether the drug was a generic or brand by indicating whether the product had been approved under an NDA or an ANDA. Debra DeYoung Tr. 3/20/07 at 231-232 (Thomas Exhibit 5). Similarly, price information sheets provided by Abbott to FDB or Red Book often contained notations as to whether the drug was brand or generic. *See* Kristen Minne Tr. 11/18/08 Exhibits 26 (Thomas Exhibit 48) and Minne 31 (Thomas Exhibit 51).

RESPONSE: Abbott disputes the materiality of the paragraph 13. Subject to and without waiving this objection, Abbott admits.

14. Abbott PPD employees knew that FDB published AWPs that were calculated at 25% above the WACs that Abbott reported. Beth Garvin-Senger Tr. 12/17/08 at 46-47 (Thomas Exhibit 1) ("In the pricing group, I would say that that was a general understanding."); Joseph Fiske Tr. 2/18/09 at 349:2 to 349:16 (Thomas Exhibit 2) (unit-dose packaging of Abbokinase only drug identified whose AWP was not calculated by FDB at 25% above WAC); Debra DeYoung Tr. 3/20/07 at 196:9 to 196:10 (Thomas Exhibit 5) (general understanding at Abbott that AWP was 125% of WAC); Kristen Minne Tr. 11/18/08 Exhibit 22 (Thomas Exhibit 47) and Minne Exhibit 24 (Thomas Exhibit 52). In training materials used within PPD, AWP was defined as "average wholesale price estimated at 125% of WAC by First DataBank." Debra DeYoung Tr. 3/20/07 Exhibit 507 (Thomas Exhibit 6); Beth Garvin-Senger Tr. 12/17/08 at 101-

102 (Thomas Exhibit 1). Similarly it was understood that if WACs were increased, then published AWPs would increase. Beth Garvin-Senger Tr. 12/17/08 at 184:7 to 184:16 (Thomas Exhibit 1).

RESPONSE: Disputed as unsupported and untrue. Abbott states that several PPD employees had understood that there appeared to be a historical mathematical relationship between WAC and AWP, but did not understand that Abbott was controlling the AWPs set by the compendia. (*See, e.g.* 1/22/09 Pavlik Dep. at 61:23-62:1, Ex. 1 (Abbott sets WAC and List Price, but not AWP).) Abbott PPD personnel understood that the compendia set AWPs based on surveys of wholesalers. (30(b)(6) Fiske Dep. at 104:17-105:5, Ex. 2.) Thomas Exhibit 6 confirms that Abbott occasionally estimated the AWPs which were set by the compendia. Paragraph 14 is unsupported to the extent the statement encompasses all "Abbott PPD employees" with the supporting testimony of a single PPD employee. Abbott informed Red Book on many occasions that it never intended to control the AWP published by the pricing compendia. (*See* Ex. 10 ("Abbott does not control how Red Book does its business nor does Abbott provide AWP or a calculated markup to establish an AWP. Consequently, Abbott concluded that there was no need to respond to Ms. Voeck's April 2003 letter. Abbott trusts that Red Book will continue to conduct its business as it sees fit."); s*ee also*, 02/20/09 Gerzel Dep. at 127:5-129:14, Ex. 10; 30(b)(6) Fiske Dep. at 142:18-144:12, Ex. 2.)

15. Abbott employees in PPD understood and were trained that the AWPs published by FDB based on Abbott's reported prices were "used as a reimbursement reference for retail pharmacy." Debra DeYoung Tr. 3/20/07 Exhibit 507 (Thomas Exhibit 6); Beth Garvin-Senger Tr. 12/17/08 at 101-102 (Thomas Exhibit 1); Joseph Fiske Tr. 2/18/09 at 347:17 to 347:21 (Thomas Exhibit 2) ("We know that a number of third party payers have pricing reimbursement that's based on AWP"). This understanding extended to Medicaid reimbursement. Beth Garvin Senger Tr. 12/17/08 at 115:12 to 115:22 (Thomas Exhibit 1); Debra DeYoung Tr. 3/20/07 at 176-177 (Thomas Exhibit 5) (knew that WACs published by FDB came from Abbott and that most Medicaid programs obtained pricing information from FDB). Abbott understood that it was important to Abbott's business that its drugs be eligible for Medicaid reimbursement, Beth Garvin-Senger Tr. 12/17/08 at 150-151 (Thomas Exhibit 1), Joseph Fiske Tr. 3/22/07 at 431:2 to 431:22 (Thomas Exhibit 55), and Abbott tracked the amount of business that was being

reimbursed by Medicaid, including for the Ery products. Beth Garvin-Senger Tr. 12/17/08 at 164-165 (Thomas Exhibit 1).

RESPONSE: Disputed as unsupported and untrue. Several PPD employees had no understanding of the reimbursement process for retail pharmacies. (*See, e.g.*, 2/19/09 Parker Dep. at 78:14-79:2; 80:9-14 ("I don't know anything about government reimbursement process."), Ex. 6; 1/22/09 Pavlik Dep. at 66:8-67:5), Ex. 1.) Some PPD employees, including Ms. Senger and Mr. Fiske, recognized a historical mathematical relationship between AWP and WAC over time. As explained by its corporate representative, however, Abbott understood that FDB and Red Book conducted surveys to determine AWP. (30(b)(6) Fiske Dep. at 102:23-103:2 (Fiske was informed by Kay Morgan of First Data Bank that "it didn't really matter what manufacturers were reporting because the data agencies did surveys of wholesalers to confirm what the AWP really should be."), Ex. 2.) Abbott disputes that AWPs could provide information about Medicaid payments for Erys since the payments were not based on AWPs. (SOAF ¶¶ 38-39, 49-50.) Abbott admits that it tracked the amount of business that was being reimbursed by Medicaid for all of its products. (12/7/08 Senger Dep. at 164:2-17, Ex. 5.)

16. Abbott employees in PPD understood that pharmacies were interested in AWPs because that was the basis on which they were reimbursed. Beth Garvin-Senger Tr. 12/17/08 at 112:2 to 112:17 (Thomas Exhibit 1). *See also*, ¶¶35, 37.

RESPONSE: Disputed as unsupported and untrue. Paragraph 16 mischaracterizes Ms. Senger's testimony. Ms. Senger testified that she assumed customers would be interested in reimbursement but that she did not "spend any time thinking about what the pharmacies were analyzing." (12/7/08 Senger Dep. at 112:15-113:5 ("I didn't think about how they were doing their own calculations to decide what product to use."), Ex. 5.)

Subject to and without waiving its objections, Abbott states that several PPD employees had no understanding of AWP, let alone its use by Medicaid programs. (30(b)(6) Fiske Dep. at

130:18-24, Ex. 2; 2/19/09 Parker Dep. at 78:14-79:2; 80:9-14 ("I don't know anything about government reimbursement process."), Ex. 6.) Fiske testified that Abbott understood that AWP was not always the basis for Medicaid payments and that states sometimes based payment on surveys or other factors. (30(b)(6) Fiske Dep. at 175:8-15 ("It's my understanding that in some cases states actually do surveys of retail pharmacies."), Ex. 2.) Fiske also testified that for multisource drugs, like Ery, states often based payments on maximum allowable costs ("MACs") which "may not bear any relationship to a published WAC or AWP." (*Id*. at 348:11-21.) Neither Abbott's price setting nor its price reporting were done with any considerations of any impact on AWPs or third-party payors. (*Id*. at 295:19-25.) PPD employees understood that it was not acceptable to discuss AWP spread with customers. (2/19/09 Parker Dep. at 97:23-98:11, Ex. 6.) Furthermore, paragraph 16 is unsupported to the extent it encompasses all of "Abbott employees in PPD" by reference to a single PPD deposition. Finally, Abbott disputes that Medicaid payments for Erys were in fact based on AWPs. (SOAF ¶¶ 38-39, 49-50.)

17. The prices at which Ery drugs within PPD were actually sold to wholesalers were called base deal prices. Joseph Fiske Tr. 2/18/09 at 318-319 (Thomas Exhibit 2). Base deal prices were sometimes limited to wholesalers who met a certain threshold volume of sales, and then the price was extended throughout the year, and at other times base deal prices were invoiced without regard to volume. Joseph Fiske Tr. 3/22/07 at 382:3 to 382:23 (Thomas Exhibit 55). Even Abbott's corporate witness admits that, at most, approximately 5% of Ery products were sold at the published WAC prices. Joseph Fiske Tr. 2/18/09 at 370:16 to 370:22 (Thomas Exhibit 2). *See also* John Christopher Pavlik Tr. 1/22/09 at 40:4 to 40:11 (Thomas Exhibit 7) (instances when customers did not meet minimum orders to qualify for base deal prices were "rare").

RESPONSE: Disputed. Wholesalers were invoiced the prices that they paid, which for Erys included WACs and sometimes Base Deal Prices. (30(b)(6) Fiske Dep. at 202:16-25, Ex. 2.) Abbott further disputes Paragraph 17 because the cited testimony does not support the statements and Ven-A-Care mischaracterizes Mr. Fiske's testimony. Abbott admits that it offered Base Deal Prices to customers that met the terms of purchasing $500 or more of Ery product on a

single invoice. (*Id*. at 206:21-207:19). A wholesaler not meeting these qualifications would pay WAC. Abbott disputes that Base Deal Prices were ever invoiced without regard to the customer's purchasing volume. (*Id*. at 61:9-63:14.)

18. Abbott employees were trained to consult the bid lists to obtain pricing in connection with solicitations, including for erythromycin products. Bid lists contained base deal prices, at least in 2000, 2001, 2002 and 2003. Donna Arnold Tr. 12/18/08 at 83-84; 91:5 to 91:8 (Thomas Exhibit 8). These base deal prices bore no consistent relationship to reported WAC or list prices, or to published WACs or AWPs, except that the base deal prices were almost always lower. Beth Garvin-Senger Tr. 12/17/08 at 28:1 to 28:11; 41-42 (Thomas Exhibit 1); Joseph Fiske Tr. 2/18/09 at 319:9 to 319:12 (Thomas Exhibit 2) (Abbott billed wholesalers for Ery's at prices lower than published WACs). Abbott routinely sent customers price lists that compared Abbott's list prices or estimated AWPs with the base deal prices. Joseph Fiske Tr. 3/22/07 at 514-515 (Thomas Exhibit 55); Fiske Tr. 3/22/07 Exhibit 536 (Thomas Exhibit 9); Debra DeYoung Tr. 3/20/07 at 191:10 to 191:21 (Thomas Exhibit 5). Russell Lehn Tr. 1/15/09 at 127-130 (Thomas Exhibit 10).

RESPONSE: Disputed. Abbott objects to and disputes the unsupported statement that its "employees were trained to consult the bid lists to obtain pricing in connection with solicitations" for Erys. Abbott further disputes Paragraph 18 because the term "consistent relationship" is vague and ambiguous and is immaterial as used. The statement erroneously assumes that there should have been a consistent relationship between a price based on terms, Base Deal Price and WAC, a list or catalog price. WAC and List Prices were prices that were generally paid by its customers. (30(b)(6) Fiske Dep at 244:21-24, Ex 2.) Abbott also disputes Paragraph 18 because the term "routinely" is vague and undefined. Abbott also objects to the contention that it sent customers price lists that compared list prices or estimated AWPs with Base Deal Prices; the cited testimony and documents do not support that Abbot sent such information, needless to say that Abbott did so "routinely."

19. Prices from wholesalers to pharmacies were, in turn, lower than the low base deal prices. Beth Garvin-Senger Tr. 12/17/08 at 41-42 (Thomas Exhibit 1). When wholesalers sold to customers at prices below the base deal prices at which the wholesalers had been invoiced, chargebacks were processed to account for the differences. Joseph Fiske Tr. 2/18/09 at 353-354 (Thomas Exhibit 2). Because of these chargebacks, the net amount paid by the wholesaler was less than the invoiced, base deal price. Joseph Fiske Tr. 2/18/09 at 353-354 (Thomas Exhibit 2).

Abbott was aware that wholesalers had programs in effect that offered prices to pharmacies that were significantly less than the reported WACs. Joseph Fiske Tr. 3/22/07 at 495-496 (Thomas Exhibit 55).

RESPONSE: Disputed. Prices offered from wholesalers to pharmacies were not always lower than Base Deal Prices. (Duggan) Abbott admits that chargebacks were used when a contracted wholesaler sold to a contracted pharmacy at a contracted price below the wholesaler's invoice price from Abbott. (30(b)(6) Fiske Dep. at 88:4-16, Ex. 2.) Abbott disputes the statement to the extent that it suggests that chargebacks were more generally used, for instance where a wholesaler sold to a customer at its own lower price. Abbott objects to and disputes the unsupported statement about what "Abbott was aware" of.

20. Base deal pricing for Ery drugs was discontinued in about 2003. Beth Garvin-Senger Tr. 12/17/08 at 201:16 to 201:21 (Thomas Exhibit 1). Although wholesalers were then billed at WAC prices, the sometimes very large difference from pharmacy prices was still accounted for through chargebacks. Beth Garvin-Senger Tr. 12/17/08 201-202 (Thomas Exhibit 1); Beth Garvin-Senger Tr. 12/17/08 Exhibit 13 and John Christopher Pavlik Tr. 1/22/09 Exhibit 17 (Thomas Exhibit 11).

RESPONSE: Disputed in part. Abbott admits that it discontinued Base Deal Prices for Ery drugs in July 2003. (30(b)(6) Fiske Dep. at 87:6-11, Ex. 2; 12/17/08 Senger Dep. at 204:18-205:3, Ex. 5.) Abbott objects to the term "very large" as vague, ambiguous, and inaccurate. Abbott admits that there often was a difference between WAC prices and contract prices, although disputes that this difference was "very large." (4/17/09 Duggan Ery Dep. at 155:6-9 (on average the dollar difference between the AWP and the average price calculated by Duggan per prescription is about $3), Ex. 149.)

21. Abbott calculated its average sales prices on at least a monthly basis, based on WAC sales less rebates, discounts, return goods allowance and any other billing adjustments. Beth Garvin-Senger Tr. 12/17/08 at 66-67 (Thomas Exhibit 1).

RESPONSE: Admitted, although Abbott notes that sales at List Prices and WACs were included in these calculations.

22. As early as 1996, Abbott established a group called the "Medicare Working Group", which was comprised of individuals from various parts of Abbott, including HPD, PPD, Ross, and Abbott's government relations/lobbying group, among others, who met or conferred telephonically on a periodic monthly basis. Haas at 53:10-13; 56:4-6; 61:20-21; 62-65; 66:1-5 & Haas Exhibit 1121; J. Miller 52:8-22; 53:1; Tootell 73:3-16. (Lavine Dec. Exhibits 110, 111, 112)

RESPONSE: Disputed. Abbott does not dispute that, for a short period of time in or around 1996, an informal group called the Medicare Working Group existed, but Abbott disputes that this group met on a monthly basis. Several of the putative members who were deposed described the group, if they remembered it at all, as a group of persons who would confer occasionally about pending issues, such as legislation, concerning Medicare. (8/30/07 Haas Dep. 89:19-90:12, 109:13-110:10 9, 263:13-15, Ex. 169; 7/30/07 Miller Dep. 54:20-55:17, 105:4-10, 112:15-114:6, 175:7-176:10, Ex. 170; 10/25/07 Tootell Dep. 55:13-57:9, 58:2-9, Ex. 171.) Abbott disputes neither that, for a short period of time in or around 1996, an informal group called the Medicare Working Group existed, nor that it consisted of persons from various divisions within Abbott. Abbott disputes the materiality of any supposed knowledge regarding Medicare reimbursement and of this working group at all. Ven-A-Care in this case is seeking damages related to Medicaid reimbursement only – Medicare issues are irrelevant, and there is no evidence that any information relevant to Medicaid was related to those responsible for pricing or pricing reporting of Erys. Ven-A-Care did not depose the two PPD individuals allegedly associated with this group.

23. In December 1996, Medicare Working Group received a document that had been referenced in a Medicare Working Group meeting by Michael Tootell. The document was entitled "Medicare Part B Payment For Drugs Average Wholesale Price Issue" and put the group on notice of the following:

a. "Currently, Medicare pays for those drugs that are not reimbursed on a prospective basis or a cost basis at the lesser of the average wholesale price or the actual acquisition cost of the drug …. Medicare pays at the average wholesale price level, because the program has not acquired acquisition cost information sufficient to establish reimbursement rates."

b. "There have been several studies and investigations into the appropriateness of using AWP as the determining factor for payment. The common conclusion of these efforts is that the use of AWP as a payment measure results in excessive reimbursement that is far out-of-line with the estimated acquisition costs of the drugs …."

c. "[T]here is some evidence that often the AWP for a drug is set at a particular level to establish third-party reimbursement, but has no relevance to any party beyond the third-party payer [sic]. For these reasons, the AWP issue is being presented and considered not as a program policy issue, but rather as an issue steeped in fraud, abuse and waste."

d. "[N]umerous people from within the industry have conceded publicly that AWP makes little sense as a basis for reimbursement."

e. "While AWP may be in excess of the acquisition cost of a drug (plus a reasonable markup), it does enable pharmacists to be reimbursed, albeit indirectly, for the necessary pharmaceutical services they do in fact provide. Since Medicare does not acknowledge the existence of these services, and thus does not provide for separate or additional reimbursement for them, the current use of AWP is the only means of paying pharmacists for what they actually do for Medicare beneficiaries."

Abbott Medicare Working Group document ABT 53263-53265. (Lavine Dec. Exhibit 97)

RESPONSE: Disputed. Abbott disputes the materiality of any supposed knowledge regarding Medicare reimbursement. Ven-A-Care in this case is seeking damages related to Medicaid reimbursement only – Medicare issues are irrelevant. Abbott disputes the assertion that each of those employees actually received the document, read it, and were somehow put "on notice" of its contents, since the record does not support such an assertion. To the contrary, the Government deposed several alleged recipients who testified that they did not recognize the document and could not recall ever receiving or reading it. (*See, e.g.*, 07/30/07 Miller Dep. 83:8-85:3, Ex. 170; 08/28/07 Babington Dep. 68:4-65:11, Ex. 172; 08/09/07 Rieger Dep. 101:10-19, 106:13-107:17, Ex. 173.) Abbott objects to the document as irrelevant and inadmissible.

Abbott does not dispute that subsections A-E of paragraph 23 contain accurate quotes from a document entitled "Medicare Part B Payment For Drugs Average Wholesale Price Issue."

Abbott notes, however, that these same portions of the document establish public and government knowledge, no later than December 1996, that "the use of AWP as a payment measure results in excessive reimbursement that is far out-of-line with the estimated acquisition costs of the drugs," that "numerous people from within the industry have conceded publicly that AWP makes little sense as a basis for reimbursement," and using "AWP . . . does enable pharmacists to be reimbursed, albeit indirectly, for the necessary pharmaceutical services they do in fact provide."

24. One Ross Products division employee, Mr. Michael Tootell, expressed his concern to Abbott in-house legal counsel about the legal exposure and potential negative consequence of AWP spreads. Tootell 199:17-22; 200:1-20; 202:1-11. (Lavine Dec. Exhibit 112)

RESPONSE: Disputed in part. Abbott does not dispute that Mr. Tootell is a former employee who worked in a division formerly known as Ross Products. At his deposition, Mr. Tootell testified that he had a discussion with an Abbott attorney regarding certain issues relating to AWP. (10/25/07 Tootell Dep. 200:3-6, Ex. 171.) The contents of that conversation, if it in fact ever happened, would be privileged and confidential. Abbott therefore objects to and moves to strike paragraph 24. Further, David Fishman, testified that he talked with Matt Fisher, Michael Tootell's boss, and Mr. Fisher does not recall any specific conversations with Mr. Tootell in which Mr. Tootel raised a concern about AWP or "AWP spreads." (03/12/08 Fishman Dep. 121:5-122:11, Ex. 174) Mr. Fishman also spoke with Brian Taylor and Melissa Pence-Levy, in-house attorneys who worked with Ross Products. Mr. Taylor did not recall having a conversation with Matt Fisher or with Mike Tootell in which a concern with AWP was raised. (03/12/08 Fishman Dep. 131:2-6, Ex. 174.) Similarly, Ms. Pence-Levy had no recollection of Mike Tootell coming to her regarding AWP subject matter in any concerned way. (03/12/08 Fishman Dep. 149:4-20, Ex. 174.)

25. PPD personnel were aware of the role that AWP spread played in influencing a providers' choice of which product to utilize when there were therapeutic alternatives. Among the discussions had by the Medicare Working Group, when PPD members Don Buell and Don Conway were both present, there was a discussion of a possible pricing change by some state programs for Lupron, to acquisition cost. Tobiason Tr. 3/28/07 Exhibit 546 - Notes dated 1/29/97. (Thomas Exhibit 12) The notes from the meeting indicate that this would present a problem for Abbott because it would take all the providers' profit out of prescribing Lupron and would result in providers instead dispensing the lower cost Zoladex product.

RESPONSE: Abbott disputes and objects to the vague and ambiguous reference to "PPD personnel," and specifically disputes that many PPD personnel, including those responsible for Ery pricing or price reporting were aware of AWPs' or AWP spreads' influence on providers' product choices, particularly with respect to purchasing Ery drugs, which were not paid based on AWP. (*See* ¶ 16.) Abbott objects to paragraph 25 as inadmissible and immaterial because it refers to Lupron, a drug not at issue and not even sold by Abbott. Abbott further states that Thomas Exhibit 12 does not conclusively establish that Mr. Buell, or Mr. Conway was present at the referenced Medicare Working Group meeting. Furthermore, Ven-A-Care fails to cite (and has no) evidence to impute any knowledge gained by Buell or Conway to PPD.

26. On October 31, 2000, Abbott's Miles White received a letter from Congressman Fortney "Pete" Stark which stated, among other things, the following:

> "The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs.
>
> "Contrary to Abbott's recent assertions in the national media, the price manipulation conduct was in no way required by or consistent with existing reimbursement laws or policies. Indeed, Abbott did not falsify published prices in connection with other drugs, where sales and market penetration strategies did not include arranging financial 'kickbacks' to health care providers." (Lavine Dec. Exhibit 66, Stark Oct 31, 2000 Letter to Miles White, page 1)

RESPONSE: Abbott does not dispute that Congressman Stark sent the referenced letter to Miles White. It is also undisputed that Abbott was not required to and did not respond to Congressman Stark's letter.

27. Abbott testified that prior to 2003 it did not understand that the False Claims Act's reach included liability for reckless or inadvertent conduct in its price reporting. Fishman 30(b)(6) 3/20/08 at 643:10-22; 644:1-10. (Lavine Dec. Exhibit 91)

RESPONSE: Disputed. Paragraph 27 does not accurately reflect the testimony cited therein. Ven-A-Care has selectively and incorrectly paraphrased Mr. Fishman's testimony. Further answering, David Fishman, one of Abbott's 30(b)(6) corporate designee from the DOJ case, but not for PPD or any issue relating to the Erys, testified that Abbott had a policy within its code of business conduct to comply with all laws, statutes and regulations including the Medicare and Medicaid fraud and abuse, False Claims Act and other Medicare-related compliance statutes. Mr. Fishman further testified that "Abbott had a – an understanding of the law as written and continued to gain insight into the interpretation . . . as more attention was placed on it and more information became – became available." (03/12/08 Fishman Dep. 233:6-12, Ex. 174.)

28. Abbott never sought guidance from HCFA, CMS or HHS-OIG about Abbott's pricing activities or to verify whether its pricing activities violated any law, including the federal False Claims Act. Abbott never asked Medicare or Medicaid officials whether it was permissible to provide customers with spread or AWP information. Fishman Rule 30(b)(6) 3/12/06 at 224:4-22; 225:1-6; 234:14-20; 240:10-22; Fishman 30(b)(6) 3/20/08 at 644:11-14. (Lavine Dec. Exhibits 90, 91). PPD representative Joe Fiske testified that Abbott did not rely on any government reports in determining how to report its Ery prices. Joseph Fiske Tr. 2/18/09 at 285:25 to 286:7. (Thomas Exhibit 2)

RESPONSE: Disputed. Paragraph 28 does not accurately reflect the testimony cited therein. Ven-A-Care has selectively and incorrectly paraphrased Mr. Fishman's testimony. The entirety of the transcript is the best evidence of Mr. Fishman's testimony. David Fishman, one of Abbott's 30(b)(6) corporate designee from the DOJ case, but not for PPD or any issue relating to the Erys, testified that Abbott did not ask Medicare or Medicaid officials whether it was it was

permissible to provide customers with spread or AWP information because it was a practice not to provide such information to customers. (03/12/08 Fishman Dep. 240:21-241:10, Ex. 174.) Paragraph 28 and the testimony cited therein also misrepresent Mr. Fiske's testimony. Mr. Fiske testified that Abbott acted in good faith by reporting to the data agencies the information requested, without any intent to influence Medicaid payments. (30(b)(6) Fiske Dep. at 188:22-189:11, Ex. 2.)

29. The only review Abbott undertook to evaluate whether its pricing practices complied with Medicare and Medicaid fraud and abuse laws was undertaken by its legal department. Abbott has claimed that the evaluation is privileged and instructed its counsel not to answer questions concerning the evaluation. Fishman 30(b)(6) 3/12/08 at 335:5-22; 336-343; 344:1-22. (Lavine Dec. Exhibit 90)

RESPONSE: Disputed. Paragraph 29 does not accurately reflect the testimony cited therein. Abbott disputes the statements in paragraph 29 because they misstate the deponent's testimony. Mr. Fishman testified, on behalf of Abbott HPD, in response to plaintiffs questions that any evaluation as to whether Abbott's pricing practices complied with Medicare and Medicaid Fraud and abuse laws would have been undertaken by Abbott's legal department and that such evaluation would be privileged. (03/12/08 Fishman Dep. 145:6-146:1; 333:12-14, Ex. 174.) Abbott disputes the materiality and admissibility of the second sentence in paragraph 29. Abbott further states that PPD reported its WAC and list prices, consistent with industry practice. (SOAF ¶ 24, 27-32.) Neither the government nor the compendia told Abbott to report different figures. (*Id*. at ¶ 26)

30. Abbott also refused, on the grounds of privilege, to provide testimonial evidence from its corporate representative concerning:

a. whether Abbott evaluated the legality of the spreads between its actual selling prices to customers and its AWPs;

b. advice regarding AWP, spread or spread marketing provided by Abbott in-house counsel to Abbott employees (even though non-legal employees

were not permitted to review or interpret federal and state statutes and regulations); and

c. advice regarding price reporting and Medicare and Medicaid fraud and abuse (including concerning the federal Anti-kickback statute and the federal False Claims Act) provided by Abbott in-house counsel to Abbott employees.

Fishman 30(b)(6) 3/12/08 at 31:20-22; 32:5-22; 33:1-19; 35:7-22; 36-39; 40:1-18; 42:20-22; 43-46; 47:1-8; 110:8-22; 111:1-7; 287:7-16; 295:2-22; 296; 297:1-21; 332:10-22; 333:1-22 (Lavine Dec. Exhibit 90).

RESPONSE: Disputed. Paragraph 30 does not accurately reflect the testimony cited therein. Further, Ven-A-Care has cited deposition testimony from the HPD corporate representative, not the corporate representative designated in this case to discuss PPD issues. Abbott disputes the materiality of the above statement and the footnote, but does not dispute that the government sought to obtain privileged information from Abbott. (03/12/08 Fishman 31:20-32:13, Ex. 174.) Abbott disputes the materiality and admissibility of the statements in paragraph 30.

31. In 2001, TAP Pharmaceuticals ("TAP") pled guilty to federal criminal charges ("TAP Criminal Case") in the District of Massachusetts, settled a civil action, and entered into a Corporate Integrity Agreement with HHS-OIG as a result of conduct including creating and marketing high spreads. TAP paid a criminal fine of $290,000,000 and civil settlement payment of $559,482,560 incident to settling two related AWP lawsuits filed in the District of Massachusetts ("TAP Civil Actions"). In 2001, Abbott had to sign a letter agreement consenting to the criminal plea and settlement. *See* Abbott Letter Agreement in TAP Case (Lavine Dec. Exhibit 94).

RESPONSE: Abbott objects to and moves to strike paragraph 31 because issues surrounding TAP Pharmaceuticals, Inc. are irrelevant to this case. (05/16/07 Hearing Transcript at 57-62, Ex. 175) (denying Government's motion to compel discovery relating to TAP as irrelevant to this case).) This is not the sort of evidence that the Court may consider in ruling on summary judgment. *See, e.g., Hillstrom v. Best Western TLC Hotel*, 354 F.3d 27, 32 (1st Cir. 2003) ("This evidence was not admissible and could not be considered in the summary judgment analysis"); *Horne v. City of Boston*, 509 F. Supp. 2d 97, 111 n.19 (D. Mass. 2007) ("A court will not

consider inadmissible evidence in ruling on a motion for summary judgment.") (citation omitted).

32. Abbott understood the needs of its target customers. Debra DeYoung Tr. 3/20/07 Exhibit 507, Pricing 101 (Thomas Exhibit 6); Joseph Fiske Tr. 3/21/07 at 130:18 to 130:22 (Thomas Exhibit 13); Abbott Laboratories, Pharmaceutical Products Division, 2004 Customer Business Development Plan, ABT_ERY-E00018196-20 (Thomas Exhibit 14); Public Health Policy & Strategy Update, ABT_ERY-E00005954-65 (Thomas Exhibit 15); Abbott Trade Sales & Development, Trade Project Summary Report 7/11/2005, ABT_ERYE00017027-30 (Thomas Exhibit 16); Amerisource Bergen customer profile, ABT_ERY-E00006011-30 (Thomas Exhibit 17); McKesson customer profile, ABT_ERY-E00005976-88 (Thomas Exhibit 18); CVS Account Overview, ABT_ERY-E00005000-04 (Thomas Exhibit 19); Abbott Laboratories, Pharmaceutical Products Division, 2004 Customer Development Plan, Kroger, ABT_ERYE00018228-36 (Thomas Exhibit 20); 2008 Trade Channel Situation Analysis, ABT_ERYE00001087-1124 (Thomas Exhibit 21); 2005 Trade Sales & Development Strategic Plan Summary, ABT_ERY-E00006305-26; National Trade Executives Humira Talking Points, ABT_ERY-E00006043-63 (Thomas Exhibit 22).

RESPONSE: Abbott objects to paragraph 32 as too vague and ambiguous to permit a proper response. Subject to and without waiving the objections, Abbott does not dispute that, to an extent, some Abbott PPD personnel attempted to understand target customers' needs. For example, the cited documents show that Abbott understood a greater need for product growth, reduced lead time, service level improvement (Thomas Exhibit 14 and Thomas Exhibit 20); and to "elevate senior relationships with [] Trade Partners in order to be engaged in discussions about future business models (Thomas Exhibit 21). Abbott disputes as unsupported and untrue paragraph 32 to the extent it implies that it understood that its target customers needed Abbott to increase spreads.

33. Various supply chain partners communicated their business interests and concerns to Abbott, describing the capabilities and benefits of partnerships between Abbott and these companies. Abbott learned these business partners were able to provide valuable market intelligence and services to assist Abbott in achieving sales. Through these business relationships, Abbott attempted to enhance its market share through marketing efforts and managerial decisions. Leader Drug Stores Advantage, Russell Lehn Tr. 1/15/09 Exhibit 15 (Thomas Exhibit 23); Theresa Parker Tr. 2/19/09 at 112-113 (Thomas Exhibit 24), Parker Exhibit 6 (Thomas Exhibit 25); Retail Buying Group Documents, Russell Lehn Tr. 1/15/09 Exhibit 11 (Thomas Exhibit 26); Potential Issues and Talking Points, ABT_ERY-E00011616-17 (Thomas Exhibit 27); the Health Strategies Group, Specialty Pharmacy Management Industry

Overview and Assessments of Leading Companies, TXTABT-E 0060660-90 (Thomas Exhibit 28); Cardinal Health document, Michael Beck Tr. 9/27/06 Exhibit 157, TXABT 34886-904 (Thomas Exhibit 29); Option Care document, Dennis Walker Tr. 4/5/07 Exhibit 581, TXABT 60942-70 (Thomas Exhibit 30); Pharmaceutical Buyers Inc. (PBI) document, Sellers Tr. 2/14/07 Exhibit 293, TXABT 453403-13 (Thomas Exhibit 31); Managed Healthcare Associates (MHA) document, Sellers Tr. 2/13/07 Exhibit 292, TXABT 370566-68 (Thomas Exhibit 32); GeriMed document, Susan Rhodus Tr. 4/26/05 Exhibit 332, TXABT 15660-63 (Thomas Exhibit 33); GeriMed document, Susan Rhodus Tr. 4/26/05 Exhibit 335, TXABT 12280-315 (Thomas Exhibit 34).

RESPONSE: Disputed. Abbott disputes any implication that Abbott attempted to focus its marketing efforts to increase its market share by marketing the spread. (12/17/08 Senger Dep. at 112:19-113:5, Ex. 5.) Abbott states it had no knowledge that any third parties were marketing the spread for the Ery products. (1/15/09 Lehn Dep. at 163:3-6; 175:25-176:2, Ex. 3; Pavlik Dep. at 103:23-104:21; 107:2-8, Ex. 1.) Abbott disputes Paragraph 33 as unsupported by the cited documents. Thomas Exhibit 25 merely consists of a request by APCI for Wholesale Acquisition Cost and "AWP listing" – without any reference to spread. There is no proof that Thomas Exhibit 26, or any document like it, was ever distributed by PPD. (1/22/09 Pavlik Dep. at 82:17-21("I know I never promoted them to my customers in that fashion"), Ex. 1.) Thomas Exhibits 27-31 are documents or presentations reviewed by HPD, not PPD. Ven-A-Care is judicially estopped from presenting evidence regarding actions taken by HPD as material evidence. Thomas Exhibit 32 is a document prepared for a managed care customer, not a customer seeking Medicaid reimbursement. Furthermore, there is no evidence that anybody at PPD received or reviewed either Thomas Exhibits 33 or 34.

34. Abbott, including PPD, developed its knowledge of third party reimbursement in several ways, including:

- employees such as Ms. April Gerzel, PPD Supervisor of Chargebacks and Memberships, and Ms. Donna Arnold, PPD Contract Analyst, who both had experience in Abbott's Home Infusion business. (Donna Arnold Tr. 12/18/08 at 10-31 (Thomas Exhibit 8)); (April Gerzel Tr. 2/20/09 at 6 (Thomas

Exhibit 35));

- the employment of reimbursement experts such as Mr. Heggie (HPD Manager, Reimbursement), Ms. Tobiason (Senior Director of Corporate Reimbursement), Mr. Rodman (HPD Home Infusion Services, Reimbursement Supervisor), Mr. Tootell (Ross, Senior Manager for Health Policy and Reimbursement) and Ms. DeYoung (PPD, Senior Manager of Strategic Pricing);

- participation in the Medicaid rebate and Supplemental rebate system (April Gerzel Tr. 2/20/09 at 13 (Thomas Exhibit 35));

- Abbott's experience as a provider in the home infusion market; Abbott's various business relationships and partnerships including pharmacy providers, group purchasing organizations and wholesalers (Cardinal Health Rx Management Conference, ABT_DOJ-E00017188-206 (Thomas Exhibit 36)); and

- from industry sources such as the National Pharmaceutical Council and the American Society of Consultant Pharmacists (ASCP) through reports made available to companies like Abbott (ABT_ERY-E00007713-50 (Thomas Exhibit 37)).

RESPONSE: Disputed. Abbott disputes the materiality of knowledge gained by HPD employees as Ven-A-Care has failed to proffer any evidence imputing that knowledge to the relevant PPD employees. Abbott admits that Ms. Gerzel and Ms. Arnold worked briefly in HPD, but denies that there is any evidence that they retained or passed along to those responsible for PPD pricing or reporting any knowledge regarding third-party reimbursement payments. Ms. Gerzel specifically denied gaining any relevant knowledge of third-party payment structure during her time working in HPD. (2/20/09 Gerzel Dep. at 6:9-9:13, Ex. 10.) Ms. Arnold served as an administrative assistant and customer representative with Home Infusion and had no responsibility for reimbursement claims. (12/18/08 Arnold Dep. at 10:5-15:24, Ex. 21.) Abbott disputes the materiality of the employment of "reimbursement experts" Heggie, Tobiason, Rodman, Tootell or De Young. Ven-A-Care has no evidence to impute any knowledge to PPD.

Abbott disputes that its signature on either federal rebate or state supplemental rebate agreements gave it knowledge of the Medicaid reimbursement process as a whole, beyond information relevant to its payments of those rebates (*e.g.* calculating AMP). Abbott admits that Thomas Exhibit 37 is a report prepared by the American Society of Consultant Pharmacists dated January 24, 2001. There is no evidence that Abbott reviewed the potential Medicaid Profit reported in Thomas Exhibit 37 or elsewhere. Moreover, it is not relevant to payments of Ery claims because it does not address FULs or MACs.

35. Abbott's knowledge of reimbursement issues included the concept of reimbursement spread and that generic buyers considered reimbursement spread in choosing which products to purchase. Debra DeYoung Tr. 3/20/07 Exhibit 507, presentation "Pricing 101" (Thomas Exhibit 6) or Beth Garvin-Senger Tr. 12/17/08 Exhibit 4 (Thomas Exhibit 38); Theresa Parker Tr. 2/19/09 at 133-135 (Thomas Exhibit 24); Pavlik e-mail, MAC List from Aetna for Ery's and Cyclosporine, ABT_ERY-E00009460-62 (Thomas Exhibit 39); Potential Issues and Talking Points, ABT_ERY-E00011616-17 (Thomas Exhibit 27).

RESPONSE: Disputed. Paragraph 35 does not accurately reflect the content of the exhibits cited therein. "Pricing 101" (attached as Thomas Exhibit 6 and 38) does not discuss marketing the spread but instead discusses the importance to customers of rebates, lower costs and partnership opportunities. According Thomas Exhibit 39, Abbott was told by its customers that it had a "lack of sensitivity to WAC in relationship to [] pricing, -" thereby contradicting Ven-A-Care's argument that Abbott was setting its prices to market the spread. Thomas Exhibit 27 does not mention Ery and Mr. Fiske had no recollection of it. (30(b)(6) Fiske Dep. at 302:16, Ex. 2.) Paragraph 35 does not accurately reflect the testimony of Ms. Parker. Ms. Parker testified that profit was one factor important to generic buyers, but said AWP spread was simply not a talking point at Abbott. (2/19/09 Parker Dep. at 97:10-98:11 ("It's not our business how they profit. We have to see our products based on the merits of our product, which have to do with its clinical effectiveness, its availability, its [] reliability…"), Ex. 6.) Mr. Pavlik specifically denied that his

review of Thomas Exhibit 39 had any impact on pricing. (1/22/09 Pavlik Dep. at 176:21-24, Ex. 1.)

36. Abbott was aware of possible reimbursement changes and attempted to impact these changes by perpetuating the current reimbursement system. Cynthia Sensibaugh Tr. 7/12/07 Exhibit 1120, ABT-DOJ 295990-92 (Thomas Exhibit 40); Rosemary Haas Tr. 8/30/07 at 29-32 (Thomas Exhibit 41); Richard Rieger Tr. 8/9/07 at 27-39 (Thomas Exhibit 42); Medicare Working Group Documents; Lobbying Documents ABT-DOJ 0295979 – 80 (Thomas Exhibit 43); David Landsidle Tr. 10/15/07 Exhibits 1138 {ABT-DOJ 296200} (Thomas Exhibit 44) and 1139 {ABT-DOJ 295996} (Thomas Exhibit 45); Rodman E-mail, Exhibit 963, TXABT 434310 (Thomas Exhibit 53). The Medicare Working Group at Abbott was created to examine Medicare and reimbursement issues, including AWP. This working group, according to Mr. Reiger, Manager of Strategic Planning at Abbott (corporate) was created to be a "crossdivisional" group within Abbott. Richard Rieger Tr. 8/9/07 at 16 (Thomas Exhibit 42). PPD's representation on this group included Mr. Don Buell, Director of Health Economics and Policy and Dr. Don Conway, Director of Epidemiology and Outcomes Research. Virginia Tobiason Tr. 3/28/07 Exhibit 546(a), 546(b); Medicare Working Group Documents (Thomas Exhibit 12).

RESPONSE: Disputed in part, and otherwise immaterial. Abbott disputes as unsupported and untrue the allegation that Abbott attempted to impact changes by perpetuating the current reimbursement system. Abbott disputes neither that, for a short period of time in or around 1996, an informal group called the Medicare Working Group existed nor that it consisted of persons from various divisions within Abbott. Abbott admits that Mr. Buell and Dr. Conway are listed as the representatives of PPD but disputes that there is any evidence that either Mr. Buell or Dr. Conway was actually aware of Medicaid payment changes or ever communicated any information they learned from the Medicare Working Group to other PPD employees who were responsible for price setting or reporting. Abbott disputes the materiality of Thomas Exhibits 40, 43, 44, 45 and 53, which concern Medicare, not Medicaid payments. Abbott disputes the materiality of any supposed knowledge regarding Medicare reimbursement and of the Medicare working group at all. Ven-A-Care in this case is seeking damages related to Medicaid reimbursement only – Medicare issues are irrelevant, and there is no evidence that any information relevant to Medicaid was related to those responsible for pricing or pricing reporting

of Erys. Abbott further disputes the testimony of Ms. Haas, contained in Thomas Exhibit 41 as immaterial, particularly to the extent that it concerns the alleged lobbying efforts of HPD, a separate division from PPD.

37. Abbott was aware that its customers were interested in AWP and customers asked Abbott to provide to them AWP information. Joseph Fiske Tr. 3/21/07 at182-183 (Thomas Exhibit 13); John Christopher Pavlik Tr. 1/22/09 at 128-129 (Thomas Exhibit 7). Abbott was also aware customers generally did not pay WAC or AWP for the Ery drugs, neither of which are representative of prices being paid in the marketplace. In fact, Abbott routinely transacted business with its customers based on contract or base deal prices and Abbott did not report these contract prices, or report lower prices when contract prices declined, to the compendia. John Christopher Pavlik Tr. 1/22/09 at 182-183 (Thomas Exhibit 7); Debra DeYoung Tr. 3/20/07 at 291-292 (Thomas Exhibit 5); Joseph Fiske Tr. 3/22/07 at 486:15 to 486:25 (Thomas Exhibit 55); Russell Lehn Tr. 1/15/09 at 62-63 (Thomas Exhibit 10); Debra DeYoung Tr. 3/20/07 at 78-79 and 191-192 (Thomas Exhibit 5); Bid Sheets, Debra DeYoung Tr. 3/20/07 Exhibits 510 (Thomas Exhibit 57), DeYoung Exhibit 511 (Thomas Exhibit 58), DeYoung Exhibit 512 (Thomas Exhibit 59), DeYoung Exhibit 513 (Thomas Exhibit 60), DeYoung Exhibit 514 (Thomas Exhibit 61), DeYoung Exhibit 515 (Thomas Exhibit 62), DeYoung Exhibit 516 (Thomas Exhibit 63), DeYoung Exhibit 517 (Thomas Exhibit 64) DeYoung Exhibit 518 (Thomas Exhibit 65); John Christopher Pavlik Tr. 1/22/09 Exhibits 17 (Thomas Exhibit 11) and Pavlik Exhibit 18 (Thomas Exhibit 66).

RESPONSE: Disputed. Although, Abbott admits that on occasion customers did ask Abbott to provide to them information including AWPs, Abbott states that company policy prohibited employees from providing AWP information to customers. (12/18/08 Arnold Dep. at 63:22-64:3 ("I was instructed that it was not a price type that we calculated. So we would refer them to First Data Bank."), Ex. 21.) Abbott also disputes paragraph 37 to the extent it claims that Abbott's customers did not pay WAC. Abbott states throughout the relevant time period, Abbott routinely had sales at WAC. (2/17/09 Fiske Dep. at 48:8-25, Ex. 2; 1/15/09 Lehn Dep. at 113:6-13, Ex. 3; Young Aff., Ex. 7 ¶ 3.) Abbott admits that certain customers qualified for special discounts, based on volume purchased or contractual agreement. (1/15/09 Lehn Dep. at 109:2-17, Ex. 3.) Abbott disputes the statement to the extent it implies Abbott was ever required to report its contract or term prices to the compendia. Abbott states that it reported the prices that it

understood were requested by the compendia. (30(b)(6) Fiske Dep. at 111:5-24; 195:7-14, Ex. 2; 2/20/09 Gerzel Dep. at 44:24-45:13, Ex. 10.)

38. Abbott understood how customers made pricing decisions based on reimbursement. The "Neoral Profit Analysis" presented a spreadsheet calculation of net profit to a provider, for Neoral compared to Gengraf. The testimony of Abbott witnesses was that this was an internal analysis, but it demonstrates an understanding of the importance of this type of reimbursement-profit analysis in marketing a generic drug. While this comparison was not made for the drugs at issue in this case, the calculation was based on AWP, an estimated reimbursement rate and actual product acquisition costs, and demonstrated a working knowledge of reimbursement profitability. Joseph Fiske Tr. 2/18/09 Exhibit 21 (Thomas Exhibit 67).

RESPONSE: Disputed. Abbott objects that paragraph 38's first sentence is so vague and general that it cannot fairly be responded to and that it otherwise is unsupported. Without waiving the objection, Abbott disputes the statement and states that Mr. Fiske explained in his deposition that the "Neoral Profit Analysis" was created to assist Abbott in determining whether to market Gengraf or its AB generic equivalent, Neoral. The modeling was shared only with those in the managed care marketing group. (30(b)(6) Fiske Dep. at 325:5-326:3, Ex. 2.) Abbott admits that it shared AWP information with managed care group, but disputes the materiality of the knowledge of its managed care group or customers. Managed care is the group that negotiates with pharmacy benefit managers ("PBMs") for rebates. (12/18/08 Arnold Dep. at 19:2-12, Ex. 21.) PBMs represent private insurers – not pharmacies or entities that are reimbursed by Medicaid. (12/18/08 Kadish Dep. at 40:5-41:15, Ex. 22.) The rebates offered to PBMs are calculated as a percentage of AWP. (30(b)(6) Fiske Dep. at 317:5-9, Ex. 2) Mr. Fiske explained that PPD shared AWPs so the PBMs could understand the value and amount of their rebates. (*Id*.)

39. Customer documents informed Abbott of the significance of spread in customer buying decisions. For example, a 1996 GeriMed Request for Proposal, from Abbott business records, prepared for bidding pharmaceutical manufacturers and suppliers (Susan Rhodus Tr. 4/26/05 Exhibit 335) (Thomas Exhibit 34) demonstrated spread was important to GeriMed members.

RESPONSE: Although Abbott admits that one document cited by Ven-A-Care mentions spread, Abbott disputes paragraph 39 as unsupported and immaterial. Ven-A-Care cites only one document, and that document did not inform Abbott that "spread" was significant in customer buying decisions.

40. Mr. Tim Bien of Omnicare (Timothy Bien Tr. 4/25/05 Exhibit 302) (Thomas Exhibit 68) demonstrated the importance of spread to Abbott's customers with his request (Timothy Bien Tr. 4/25/05 Exhibit 301, TXABT 42077) (Thomas Exhibit 69) in May of 2001 to be made "whole" by Abbott (HPD) after a $10.5 million loss that Omnicare experienced after the 2000 DOJ price changes and the May 2001 HPD price decreases. About this time, Omnicare sponsored a "Pharmaceutical Industry Day" bringing in manufacturer representatives from across the country to present to the pharmaceutical industry issues important to Omnicare resulting from decreased levels of reimbursement. Timothy Bien Tr. 4/25/05 at 103-104 (Thomas Exhibit 70). Mr. Dave Molnar, PPD's National LTC Manager, attended Omnicare's Pharmaceutical Industry Day. Timothy Bien Tr. 4/25/05 Exhibit 313 (Thomas Exhibit 71).

RESPONSE: Although Abbott admits that one document cited by Ven-A-Care mentions spread, Abbott disputes paragraph 40 as unsupported and immaterial. Abbott disputes that Mr. Bien's request demonstrated the importance of spread to Abbott's customers. The price change about which Mr. Bien was complaining had no connection to Abbott PPD. Mr. Molnar's attendance at Omnicare's Pharmaceutical Industry Day is immaterial to Abbott's pricing and marketing practices.

41. Other customer documents also demonstrated that Abbott was concerned about customer reimbursement. In an October 7, 2002, email to Abbott (Debra DeYoung Tr. 3/20/07 Exhibit 509, TXABT-E 0033830 (Thomas Exhibit 72)) Mr. David King of Safeway wrote: "*I believe your company has a genuine concern for our reimbursement….*" Abbott was aware from Cardinal documents in Abbott's possession that spread and reimbursement were topics addressed by Cardinal to its customers. Joseph Fiske Tr. 3/21/07 at 153-156 (Thomas Exhibit 13)

RESPONSE: Disputed and unsupported. The cited documents absolutely do not support that Abbott PPD was "concerned about customer reimbursement." Mr. King's email comment is inadmissible hearsay and does not in fact establish that Abbott was concerned about "customer reimbursement" under Medicaid, and Abbott disputes Ven-A-Care's statement. The comment amounts to puffery or persuasion in order for Mr. King to Abbott to change WAC prices to

Safeway's benefit, which Abbott in fact did not do. Mr. Fiske's testimony merely established that there was a Cardinal presentation in Abbott's file; Ven-A-Care presents no evidence about the presentation – *e.g.*, whether the referenced page was presented or if the attending Abbott person (assuming there was one) said that Cardinal should skip the page because Abbott doesn't care about spread issues. The referenced testimony establishes nothing material. In fact, all deposed PPD witnesses stated unequivocally that PPD did not care about AWP or spread issues. (30(b)(6) Fiske Dep. at 304:5-305:7, Ex. 2; 1/15/09 Lehn Dep. at 217:18-218:23, Ex. 3; 2/19/09 Parker Dep. at 97:23-98:11, Ex. 6.)

42. Customers asked for and Abbott provided AWP information. By combining AWP information, obtained from Abbott and other sources, with acquisition costs, customers had the necessary information for determining a product's spread. This allowed customers to optimize their profitability with respect to purchasing decisions. Multiple computer systems, including Abbott's own CHIP system (*see also*, for example, GeriMed Emphasys, Susan Rhodus Tr. 4/26/05 Exhibit 351 (Thomas Exhibit 73)) provided either a direct calculation of the spread or provided AWP and price so that spread could be easily calculated. Cardinal's corporate representative, Donald Lyle, testified at length on this topic and described pharmacies' widespread use of software to evaluate reimbursement and spreads. Donald Lyle Tr. 7/22/08 at 138-140, 161 & 181-188. (Thomas Exhibit 74)

RESPONSE: Disputed. Ven-A-Care cites no evidence that Abbott provided AWP information to customers. Several PPD employees testified that they did not send AWP to customers. (1/15/09 Lehn Dep. at 76:20-15 (in filling out product information for customers, he did not find that customers sought AWP information.); *id*. at 84:15-19 (did not feel necessary to provide AWP information to customers during his tenure in PPD pricing) Ex. 3; 2/19/09 Parker Dep. at 97:23-98:11 (would not discuss AWP spread with customers), Ex. 6; 2/20/09 Gerzel Dep. at 109:23-110:7 (general policy of Abbott not to provide AWP information), Ex. 10; 1/22/09 Pavlik Dep. at 128:9-129:3 (when he received AWP requests from customers he would tell them to go look it up in Red Book), Ex. 1.) Abbott was not aware that its customers were communicating AWP to pharmacies. (1/22/09 Pavlik Dep. at 104:9-21 (had no idea that Cardinal was

communicating AWP information to pharmacies); *id*. at 114:6-14 (never talked about AWP with Cardinal – focused on a competitive purchasing price for them); *id.* at 225:21-226:4 (had no idea that Cardinal was submitting AWP information), Ex. 1.) Abbott provided AWPs to managed care customers in order for them to understand the value of their rebates, but that is immaterial to this case. (RSOF ¶ 38; 30(b)(6) Fiske Dep. at 317:2-9, Ex. 2; 12/18/08 Arnold Dep. at 61:14-62:24, Ex. 21.) Abbott further disputes the materiality of Thomas Exhibit 73 as it pertains to the Comprehensive Homecare Information, a program used exclusively by Home Infusion with no connection to PPD. (6/28/07 Kreklow Dep. at 288:17-20, Ex. 176.) Moreover, Abbott disputes that "[b]y combining AWP information . . . with acquisition costs, customers had the necessary information for determining a product's spread [and] optimize their profitability with respect to purchasing decisions." Medicaid payments for the Erys were not even based on AWPs. (SOAF ¶¶ 38-39, 49-50.)

43. Fiske testified, as the PPD representative, that Abbott understood that pricing compendia calculated AWPs they published off of WAC prices that Abbott reported, and that many Medicaid programs set their reimbursement based on the published AWPs. Joseph Fiske Tr. 3/21/07 at 76 – 81 (Thomas Exhibit 13). Abbott PPD provided AWP information to customers at least before the AWP policy was adopted. Joseph Fiske Tr. 3/21/07 at 108-109 (Thomas Exhibit 13). Abbott, including PPD, was aware that some customers evaluated the reimbursement amount they would receive, i.e., the spread, when determining which products to purchase. Joseph Fiske Tr. 3/21/07 at 122-123 (Thomas Exhibit 13); (when Abbott decided not to lower Ery prices in 2001, Fiske indicated there could be negative sales volume impact if reported prices were lowered) (Michael Sellers Tr. 3/16/08 30(b)(6) at 243-246) (Thomas Exhibit 88). Prior to Abbott's 2004 policy against providing AWP information, Abbott did provide AWPs when requested by customers in the contracting context. Joseph Fiske Tr. 3/21/07 at 174-176 (Thomas Exhibit 13). Abbott was involved in preparing and generally familiar with documents re Gengraf that depict spread or reimbursement margin. Joseph Fiske Tr. 3/21/07 at 250-253 (Thomas Exhibit 13).

RESPONSE: Disputed. Paragraph 43 does not accurately reflect the testimony cited therein. Mr. Fiske testified that Abbott understood the pricing compendia's practices as related by Ms. Morgan, from First DataBank. Ms. Morgan explained that First DataBank did not solely rely on WAC but rather did independent surveys of wholesalers to set AWP. (30(b)(6) Fiske Dep. at

102:6-103:2, Ex. 2.) Mr. Fiske also explained that he understood that AWP was not the sole basis for calculating reimbursement by State Medicaid programs. (*Id*. at 348:13-18.). Ven-A-Care's statement that Abbott was aware that some customers evaluated the payment amount or spread when determining which products to purchase is unsupported and overstated. Mr. Fiske testified that PPD "had an understanding that customers needed to at least break-even and, presumably, cover all of their costs and that reimbursement was important to that extent." (20 (b)(6) Fiske Dep. 3/21/07 130:18-22, Ex. 2.) Other PPD employees had no understanding of the connection between published prices and Medicaid payments. (1/22/09 Pavlik Dep. at 66:8-67:2, Ex. 1.) Medicaid payments for Ery were often based on prices other than AWP, either by the operation of a MAC or FUL. (SOAF ¶ 37-38, 46-50) Abbott disputes that Abbott was "involved in preparing and generally familiar with documents re: Gengraf that depict spread or reimbursement margin" as unsupported and immaterial. Mr. Fiske testified that no such analysis was performed for the Ery drugs. (30(b)(6) Fiske Dep. at 355:9-25, Ex. 2.)

44. PPD was responsible for marketing Gengraf, the Erythromycin product line, and the Ross division's Pediazole. These drugs were marketed as generic medications. In contrast, most of the PPD product line was comprised of single source medications which were marketed based, in part, on clinical features and the marketing was focused on prescribing physicians and managed care organizations. Abbott marketed the Erythromycin products differently than other PPD products by focusing the sales message to drug purchasers rather than prescribers and emphasized low purchase prices including the "base deal" price. (Joseph Fiske Tr. 2/18/09 at 346-347 (Thomas Exhibit 2); Debra DeYoung Tr. 3/20/07 Exhibit 520, TXABT 244823-843 (Thomas Exhibit 75))

RESPONSE: Abbott admits that PPD was responsible for marketing Gengraf, the Erythromycin product line and Pediazole and that these drugs were sold as generic medications. Abbott disputes the contention that it focused on low purchase prices like the base deal price; Abbott focused on several factors to sell its products, including full product line availability, quality of product, reliability of distribution and distribution cost. (1/15/09 Lehn Dep. at 20:21-21:1; 217:18-218:23, Ex. 3.) Abbott states that it did not attempt to offer the lowest price in the

market, instead it focused on its full product line and competitive pricing. (SOAF ¶ 12, 17.) During the relevant time period, the Ery drugs were well established in the market place and there was less need to focus on clinical features. (30(b)(6) Fiske Dep. at 347:11-19, Ex. 2.) Abbott admits that there was in fact more price competition for its Ery products because there were multiple sources of erythromycins, in contrast to the other drugs on the PPD line which were single source drugs. (12/17/08 Senger Dep. at 23:1-24:3, Ex. 5) Abbott states that the issue of how Ery was marketed and whether it was marketed in relation to the spread is an issue that is disputed and was the subject of expert testimony. (*See* Expert Report of Brian Reisetter at ¶ 36, Ex. 11.) Abbott states that this is a material fact that is in dispute.

45. Abbott communicated to customers its low Ery prices and the associated AWPs used to determine reimbursement spreads. For example, Debra DeYoung Tr. 3/20/07 Exhibit 520 (Thomas Exhibit 75) revealed how Abbott carefully considered and analyzed its Erythromycin pricing to its customers. In this 1995 memo concerning various retail buying groups, Bob Rochelle, the Assistant Market Manager for Managed Care, discussed various tiered pricing for different Abbott Ery products to chain and retail buying groups (RBGs). A memo describing Abbott's RBG Mail Order Program listed as its objective the influencing of RBG member pharmacies to order Abbott erythromycin products. Attached as part of the circulated packet were templates on Abbott letterhead for the RBGs to use promoting Abbott Ery products to their members based on a comparison between the listed, published AWPs for the products and the price that the RBG member would pay to obtain the product. Debra DeYoung Tr. 3/20/07 Exhibit 520, TXABT 244843 (Thomas Exhibit 75). For example, the list included AWPs for Ery Filmtabs of $21.92, $104.12 and $189.57 for the 100, 500 and 1000 size packages respectively, while prices listed elsewhere in the packet for the RBG for the same products were $12.95, $62.82 and $121.75, less approximately 10% further discounts off list for high percentage utilization. Ery Tabs, NDC 6304-13, 6304-53 and 6321-13, for different strengths and package sizes, were listed with AWPs of $6.45, $31.29 and $14.30, while the price list for the RBGs listed $23.75, $112.81 and $40.10 for the same products, again with additional discounts noted. Debra DeYoung Tr. 3/20/07 Exhibit 520, TXABT 244843, 244832 (Thomas Exhibit 75).

RESPONSE: Disputed. Abbott admits that it considered and analyzed its prices and communicated those prices to its customers. Abbott disputes, however, that it communicated AWP information or any information to its customers to determine reimbursement spreads. Abbott admits that Thomas Exhibit 75 is a memo discussing the RBG Mail Program. Abbott

objects to the implication and disputes that Thomas Exhibit 75 was ever distributed to RBG members – Ven-A-Care has no evidence on this point other than a draft document; no Abbott PPD employee testified that the form was used; and discovery uncovered no completed form and no provider's or RBG's knowledge of the form. Ven-A-Care is simply comparing apples to oranges by comparing prices listed at different parts of "the packet for the RBG." (Pavlik Dep. at 83:17-21, (When asked whether he promoted the spread Mr. Pavlik testified, "I know I never promoted them to my customers in that fashion") Ex. 1.) Abbott states that it did not market the spread. (30(b)(6) Fiske Dep. at 304:5-305:7, Ex. 2; 1/15/09 Lehn Dep. at 217:18-218:23, Ex. 3; 2/19/09 Parker Dep. at 97:23-98:11, Ex. 6.)

46. In about 2003, competition for the Ery line in the marketplace decreased and Abbott took price increases on some of the Ery products ranging from about 20 percent to 150 percent on the Erythromycin base, Erythromycin stearate and Ery-Tab. (Joseph Fiske Tr. 2/17/09 at 48-49) (Thomas Exhibit 54) Prices were not increased on all the Erythromycin products, but Abbott decided to discontinue base deal pricing completely. Joseph Fiske Tr. 2/17/09 at 48-49 (Thomas Exhibit 54). Joseph Fiske Tr. 2/17/09 Exhibits 2 (Thomas Exhibit 76) Fiske Exhibit 3 (Thomas Exhibit 77) and Fiske Exhibit 4 (Thomas Exhibit 78). Mr. Fiske originally testified the Ery prices were changed due to government investigations into pricing, but, two years later he amended his testimony and stated that he no longer believed the government investigation was the reason for the Ery price changes. Joseph Fiske Tr. 2/17/09 at 213-214 (Thomas Exhibit 54) The discontinuation of base deal pricing was significant in that prior to the 2003 Ery price changes, wholesalers were routinely invoiced at base deal prices and after this time wholesalers were invoiced at WAC. Joseph Fiske Tr. 2/17/09 at 87-88 (Thomas Exhibit 54) From July 2003, to this day, PPD reports WACs for the Ery products that are not representative of prices being paid in the marketplace by pharmacies or costs to wholesalers.

RESPONSE: Disputed in part and admitted in part. Abbott admits that in mid-2003, upon expiration of its contracts for Ery base, Ery stearate and Ery-Tab, it did "a significant evaluation of the competitive situation" and took price increases for those products that ranged from 20 percent to 150 percent. (30(b)(6) Fiske Dep. at 50:15-22, Ex. 2.) Abbott also admits that at the same time a decision was made to eliminate base deal pricing. (*Id*. at 51:18-19.) Abbott disputes the contention that its reported WAC were not representative of prices paid by customers.

(1/15/09 Lehn Dep. at 215:8-10, Ex. 3; 12/17/08 Senger Dep. at 173:18-174:8 ("If somebody came to use directly and wanted to buy a case, they would pay us WAC.") Ex. 5.)

47. Abbott made pricing information, including AWP pricing, available in the marketplace in many ways, (April Gerzel Tr. 2/20/09 at 20-21 (Thomas Exhibit 35)) including: the reporting of prices to the Medicaid Administrators (April Gerzel Tr. 2/20/09 at 21-35 (Thomas Exhibit 35); Theresa Parker Tr. 2/19/09 at 60-61 (Thomas Exhibit 24)); price reporting to the pricing compendia (Joseph Fiske Tr. 2/17/09 Exhibit 9 (Thomas Exhibit 79); April Gerzel Tr. 2/20/09 at 23-25 (Thomas Exhibit 35)); discussions between Abbott sales personnel (and Trade Relations) and customers Joseph Fiske Tr. 3/21/07 at 102, 108, 176, 216 (Thomas Exhibit 13); Theresa Parker Tr. 2/19/09 at 56-58 (Thomas Exhibit 24); through retail stocking sheets (Joseph Fiske Tr. 2/18/08 at 317 (Thomas Exhibit 2); Debra DeYoung Tr. 3/20/07 at 191 (Thomas Exhibit 5)); responses to customer bid requests (Joseph Fiske Tr. 2/18/09 at 317(Thomas Exhibit 2)); pharmaceutical wholesalers; and group purchasing organizations (April Gerzel Tr. 2/20/09 at 21-48 (Thomas Exhibit 35)).

RESPONSE: Disputed in part and admitted in part. Abbott disputes the contention that it provided AWPs. At times before 2001, Abbott made limited communications of estimated AWPs. (2/19/09 Parker Dep. at 56:3-13, Ex. 6.) Abbott admits that it provided AWP information to its managed care customers, but disputes the materiality of the knowledge of its managed care group. Managed care is the group that negotiates with pharmacy benefit managers ("PBMs") for rebates. (12/18/08 Arnold Dep. at 19:2-12, Ex. 21.) PBMs represent private insurers – not pharmacies nor entities that are reimbursed by Medicaid. (12/18/08 Kadish Dep. at 40:5-41:15, Ex. 22.) The rebates offered to PBMs are calculated as a percentage of AWP. (30(b)(6) Fiske Dep. at 317:5-9, Ex. 2.) Mr. Fiske explained that PPD shared AWPs so the PBMs could understand the value and amount of their rebates. (*Id.*).

48. Various group purchasing organizations, retail buying groups (RBGs) and wholesalers (such as Cardinal Health, McKesson and Amerisource Bergen) communicated market price and spread information about Abbott's products to their customers through value added services. These services included, for example, computer programs such as the GeriMed "Emphasys" software and the "CardinalSource" preferred generic program. Abbott was aware of the capability of the marketplace to provide pricing information to providers, including spread comparisons. Cardinal Health presentation (Michael Beck Tr. 9/27/06 Exhibit 157, TXABT 34886 (Thomas Exhibit 29), at slide 9; the Pharmaceutical Buyers, Inc. (PBI) "Missed Opportunity" report capability (Michael Sellers Tr. 2/14/07 Exhibit 293, TXABT 453403 (Thomas Exhibit 31)); Managed Healthcare Associates, Inc. (MHA) promotional piece

describing the AccuSpread program, VTP083-4880; MHA Associates, Inc. December 1, 2000, letter (Michael Sellers Tr. 2/13/07 Exhibit 292, TXABT 370566 (Thomas Exhibit 32)), in which MHA tells Abbott that MHA is sending out a request for proposals where MHA will make two awards, "*one for the lowest cost and one for the best spread.*" Further, Abbott created business relationships with and communicated pricing information with these supply chain partners. (April Gerzel Tr. 2/20/09 at 35-37 (Thomas Exhibit 35)) Through these business relationships, Abbott was able to increase awareness of the reimbursement spreads important to its customers.

RESPONSE: Disputed. Abbott disputes the materiality of the fact that "various group purchasing organizations, retail buying groups and wholesalers" communicated market price and spread information without the additional proof that Abbott was actually aware of and condoning that practice, which Abbott disputes. (1/15/09 Lehn Dep. at 163:3-6; 175:25-176:2, Ex. 3; 1/22/09 Pavlik Dep. at 103:23-104:21; 107:2-8, Ex. 1.) The contention that this practice was done with the intention to "increase awareness of the reimbursement spreads important to its customers" is false and unsupported by the evidence cited. Support for this statement is not found in either Thomas Exhibits 29 or 31, which concern the marketing practices of HPD – not PPD. Abbott admits that, as evidenced by Thomas Exhibit 32, managed care customers requested and received AWP information, but disputes the materiality of the knowledge of its managed care group. Managed care is the group that negotiates with pharmacy benefit managers ("PBMs") for rebates. (12/18/08 Arnold Dep. at 19:2-12, Ex. 21.) PBMs represent private insurers – not pharmacies nor entities that are reimbursed by Medicaid. (12/18/08 Kadish Dep. at 40:5-41:15, Ex. 22.) The rebates offered to PBMs are calculated as a percentage of AWP. 30(b)(6) Fiske Dep. at 317:5-9, Ex. 2.) Mr. Fiske explained that PPD shared AWPs so the PBMs could understand the value and amount of their rebates. (*Id*.) Finally, Abbott denies that it or anyone else could communicate "reimbursement spreads" for the Erys because Ery claims were often paid based on state MACs which were opaque, and raising reported prices for the Erys would not impact such spreads. (SOAF ¶ 47-50, 53.)

49. In a marketing planning document (John Christopher Pavlik Tr. 1/22/09 Exhibit 1) (Thomas Exhibit 80) Abbott describes the steps to be completed in preparing a new product launch including marketing tools such as a Market Information Sheet, a New Product Information Sheet, and a Wholesale Stocking Sheet. The Wholesale stocking sheet included within the set of tasks to be completed with respect to the product launch, price reporting to state Medicaid's and the compendia. Further, the Wholesale pricing sheet was to contain pricing columns including 'estimated AWP' and a blank 'wholesale price' column.

RESPONSE: Admitted. This statement is immaterial because the Erys at issue were not new products launched during the relevant claims period.

50. In about 2004, a general policy was put in place at Abbott prohibiting discussions of spread with customers. (Joseph Fiske Tr. 3/21/07 at 85 (Thomas Exhibit 13); Joseph Fiske Tr. 2/18/09 Exhibit 20 (Thomas Exhibit 81)). Ms. Tobiason, who worked on developing the policy, could not recall any prior policy prohibiting reimbursement and spread discussions. In addition to the policy document, storyboards (Joseph Fiske Tr. 3/21/07 Exhibit 523, TXTABT-E0065053-68 (Thomas Exhibit 82)) for training modules prepared and used by Abbott trained employees on this policy as well as other fraud and abuse issues. This is consistent with Abbott employees who testified that after this point in time they no longer discussed AWP with customers. However, as noted above, there were mechanisms established in the marketplace that continued to enable pharmacies to identify and evaluate reimbursement spreads without the need for Abbott to explicitly discuss this issue with its customers.

RESPONSE: Disputed in part and admitted in part. In 2004 a written policy was established at Abbott prohibiting employees from providing AWP information to customers other than managed care customers. (Fiske Exhibit 20, Ex. 177.) Abbott disputes that the prohibition of sharing AWP or "spread" was a new policy "put in place" in 2004. Rather, several Abbott PPD employees testified that, well before 2004, Abbott had a general policy in place which prohibited the sharing of AWP or spread with customers. (12/7/08 Senger Dep. at 223:10-224:11; 227:20-228:15 ("I think as far back as I can remember while I was in the pricing group that was told to us that we do not set AWP and we should not be disseminating it."), Ex. 5; 1/22/09 Pavlik Dep. at 133:7-134:13 (instruction not to discuss AWP came from Fiske in the late 90's) Ex. 1.) Prior to and after the general policy was reduced to writing, Abbott employees did not discuss AWP or spread with customers. (30(b)(6) Fiske Dep. at 304:5-305:7, Ex. 2; 1/15/09 Lehn Dep. at 217:18-218:23, Ex. 3; 2/19/09 Parker Dep. at 97:23-98:11, Ex. 6.) Abbott denies that Abbott

utilized directly or indirectly any mechanisms to enable pharmacies to identify and evaluate "reimbursement spreads." (2/20/09 Gerzel Dep. at 131:11-24, Ex. 10; 1/22/09 Pavlik Dep. at 230:11-232:5, Ex. 1; 1/15/09 Lehn Dep. at 163:3-6; 175:25-176:2, Ex. 3.)

51. Throughout the relevant time period, Abbott maintained large spreads between its published prices for Ery products and the prices at which customers actually purchased those products. See Declaration of Ian Dew and Exhibits thereto.

RESPONSE: Disputed. Abbott disputes that it only had sales at contract prices. There were actual sales at List Price. (1/15/09 Lehn Dep. at 100:14:14-22 (When stores "ran out of a product and needed to get it before they were reimbursed by their own distribution centers, they purchased at list."); *id.* at 113:6-13 ("not every pharmacy belonged to a retail buying group."); *id.* at 214:23-215:6) Ex. 3.) There were also actual sales at WAC. (1/15/09 Lehn Dep. at 215:8-10, Ex. 3; 12/17/08 Senger Dep. at 173:18-174:8 ("If somebody came to use directly and wanted to buy a case, they would pay us WAC.") Ex. 5.) Sales data shows that the sales at List Price and WAC were real and significant. (Young Aff., Ex. 7 at ¶ 3.) Abbott further disputes the contention that the difference between its contract prices and published prices resulted in "large spreads." The spreads were not larger than the government expected for these products, and in fact shrunk during the relevant period.

52. Ven-A-Care's expert, Mark G. Duggan, analyzed the transaction data produced by Abbott in this case. The transaction data is a copy of the data used by Abbott in the ordinary course of business. Among other things, Dr. Duggan used Abbott's transaction data to analyze the prices at which Abbott products were being sold directly by Abbott to customers and the prices at which the Abbott products were being re-sold by wholesalers and distributors to end customers.

RESPONSE: Dr. Duggan's work cannot form the basis of any reliable calculations, because it is inherently defective and should be struck on *Daubert* grounds (*See* Dkt. 6443.) Abbott does not dispute that Dr. Duggan purported to analyze the transaction data produced by Abbott or that the transaction data is used in the ordinary course of business.

53. The damages calculations performed by Prof. Duggan took into account the use of MACs or FULs by State Medicaid programs. The methodology essentially "readjudicated" each of the claims in the same manner as would have been done under the applicable reimbursement algorithm if the more accurate prices been reported by defendants. *See* Declaration of Mark G. Duggan, Ph.D., in Support of the United States' Motion for Partial Summary Judgment, ¶¶ 43-46 (Exhibit 41 to Henderson Declaration (Docket No. 6310)).

RESPONSE: Disputed. Dr. Duggan's work cannot form the basis of any reliable calculations, because it is inherently defective and should be struck on *Daubert* grounds (*See* Dkt. 6443.) Abbott admits that Dr. Duggan purportedly took into account MACs or FULs, but disputes that he did so correctly for the reasons stated in Dkt. 6443, which are incorporated herein..

54. There were wide variations in both the dollar amount and the percentage calculation of spread for any given NDC (*See, e.g.*, Dew Exhs. 1, 10, and 15, showing, respectively, dollar spread ranges for specific NDCs of $7.95 - $14.68 and percentage spreads from 60.57% to 153.71%; $11.62 - $18.52 and 98.91% to 255.55%; $5.72 - $8.00 and 165.95% to 413.78%). Within a given drug code, the percentage spread often varied significantly for different package sizes. (*See, e.g.*, Dew Exhs. 29-31, for NDCs 00074-6346-19, -20, and -38, respectively, showing spread percent ranges from 122.05% - 179.22%; 78.24% - 172.42%; 74.41% - 125.65%). Even at a given point in time, the spread percentage could vary markedly within a drug code. (Again, looking at NDC 00074-6346-19, -20, and -38, depicted on Dew Exhs. 29-31, the percentage spread on the different size packages ranged from 134.04% to 132.76% to 88.79% in 1996 quarter 1, from 126.15% to 143.13% to 74.41% in 1998 quarter 1, and from 122.58% to 170.80% to 78.30% in 2002 quarter 1). In parallel litigation previously proceeding in Texas state court, Abbott submitted an expert report acknowledging the extreme difficulty of the government (or other third party payors) procuring actual acquisition costs and needing instead to work from published or reported prices. *See* Report of Marv Shepherd ¶¶ 21, 29 and 43 (Thomas Exhibit 94).

RESPONSE: Disputed. Abbott states that the variations between its contract prices and the AWPs published by the compendia were not wider than the differences the government reasonably would have expected. (SOAF ¶¶ 62-80) The spreads calculated in paragraph 54 are exaggerated. For example, based on Ven-A-Care's method of calculating spread, even if a drug's AWP is only 5% more than the transaction price, Ven-A-Care would claim that drug has a 105% spread. A more accurate method to calculate spread is (AWP-AAC)/AAC. Dew Exhs. 1, 10 and 15 would show respectively dollar spreads of 38%-60%; 49%-71% and 62%-79%. Abbott further states that the difference in percentage spreads is completely dependent on how

many purchases for that NDC occur at each of the different price points (*e.g*. WAC vs. discounted contract price). Abbott disputes the materiality of Thomas Exhibit 94, in light of the extensive testimony provided by state Medicaid officials regarding their practices of obtaining actual acquisition costs directly from pharmacists. (SOAF ¶ 49.)

55. Medicaid is a joint federal-state program to assist the poor, elderly, and disabled in obtaining medical care. 42 C.F.R. § 430.0 (2009). Under the Medicaid Act, which is Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 - 1396v, the federal government provides financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan approved by the U.S. Department of Health and Human Services ("HHS"). 42 U.S.C. § 1396; 42 C.F.R. §§ 430.0, 430.10 - 430.20 (2009). One requirement is that the states have a State Plan that includes a methodology for reimbursing health care providers, including pharmacies and other providers that dispense drugs to Medicaid enrollees. 42 U.S.C. §§ 1396a(a), 1396d(a). A declaration authenticating the state plans produced by the United States in this case is attached to the United States' Local Rule 56.1 Statement of Undisputed Material Facts submitted with the Common Brief on Summary Judgment. Henderson Common Declaration. (Henderson Common Exhibit 44 (Declaration of William S. Lasowski))

RESPONSE: Admitted.

56. Federal regulations require that state Medicaid programs' payment for drugs not subject to Federal Upper Limits not exceed, in the aggregate, the estimated acquisition cost of the drug plus a reasonable dispensing fee established by the agency. 42 C.F.R. § 447.331. For purposes of this regulation, the term "estimated acquisition cost" was defined as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301. This definition did not change during the relevant time period and was also incorporated into many State regulations concerning reimbursement for Medicaid drugs.

RESPONSE: Ven-A-Care provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 56 could be read to state undisputed or material facts, they are disputed. States, not the federal government, set the rate at which they pay pharmacies for dispensing drugs to Medicaid recipients. The federal government helps states provide covered services, such as drugs, to Medicaid recipients. The federal government does not dictate the formulae that states use to determine the amount that they will pay pharmacies, or prescribe limits on the state

payments to pharmacies. The federal regulations cited by Ven-A-Care establish guidelines governing the federal government's financial assistance to the state Medicaid programs relating to their payments for drugs.

Abbott states that the federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* 42 U.S.C. § 1396a(a)(30)(A).)

57. State Medicaid program employees attempted to determine EAC in accordance with the federal regulation defining EAC as the "agency's best estimate of the price generally and currently paid by providers." (*See, e.g.*, Lavine Decl. at Ex. USAbt-K, D. Campana Dep. at 266-268 (Alaska); Ex. USAbt-C, S. Bridges Dep. at 29-31 (Arkansas); Ex. USAbt-D, A. Chapman Dep. at 307:4-310:16 (Colorado); Ex. USAbt-E, J. Dubberly Dep. at 39-42 (Georgia); Ex. USAbt-F, J. Parker Dep. at 32-34 (Illinois); Ex. USAbt-H, G. Cheloha Dep. at 350-353 (Nebraska); Ex. USAbt-P, M. Clifford Dep. at 209-210 (New Hampshire); Ex. USAbt-Q, E. Vaccaro Dep. at 35 (New Jersey); Ex. USAbt-R, L. Weeks Dep. at 32-34 (North Carolina); Ex. USAbt-AA, J. Young Dep. at 54 (Rhode Island); Ex. USAbt-V, L. Iverson Dep. at 162 (South Dakota); Ex. USAbt-J, A. Rugg Dep. at 366 (Vermont); Ex. USAbt-S, B. Tomlinson Dep. at 31-33 (Virginia); Ex. USAbt-Z, R. Homar Dep. at 390 (Wyoming); and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 69:9-71:22 (Washington)).

RESPONSE: Disputed. The record evidence in this case shows that many state Medicaid programs paid intentionally set ingredient cost payments above the "best estimate of the price generally and currently paid by providers" for several reasons, including ensuring access to care (SOAF ¶ 86); to incentivize the use of generic medications (*id.* ¶ 96); feedback and pressure from providers (*id.* ¶ 81); and to compensate for inadequate dispensing fees. (*Id.* ¶ 92, 94.)

58. Many State Medicaid program employees testified that they understood AWP to be defined according to its plain meaning (*See, e.g.*, Ex. USAbt-C, S. Bridges Dep. at 63-64 (Arkansas)); that they understood AWP to be "an average of wholesale prices for a particular product" (Ex. USAbt-Q, E. Vaccaro Dep. at 70-72 (New Jersey)); that they believed there was a predictable relationship between the published AWPs and actual market prices (*See, e.g.*, Ex. USAbt-H, G. Cheloha Dep. at 341 (Nebraska); Ex. USAbt-O, L. Farrand Dep. at 282-284, and Ex. USAbt-P, M. Clifford Dep. at 203 (New Hampshire); and Ex. USAbt-J, A. Rugg Dep. at 357-358 (Vermont)).

RESPONSE: Disputed. State Medicaid Officials testified regarding their knowledge of spreads between acquisition cost and published AWPs, AWPs were not a reliable source of market prices for generic drugs, and that spreads were much greater for generic drugs than for brand drugs. (SOAF ¶ 61, 84, 94, 95)

59. State Medicaid programs required accurate, current and comprehensive pricing information in order to process many hundreds of thousands if not millions of claims for reimbursement on many thousands of different products. (Henderson Common Exhibit 10 (9/23/2008 Hillblom Dep. (California)), at 94:22 - 95:18); Henderson Common Exhibit 11 (12/15/2008 Dubberly Dep. (Georgia)), at 61:5-62:16; Henderson Common Exhibit 12 (11/18/2008 Parker Dep. (Illinois)), at 62:5 - 64:9, 67:5 -68:16; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:7 - 346:18; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:13; Henderson Common Exhibit 15 (12/15/2008 Stevens Dep. (New Mexico)), at 312:4 -315:22; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 101:2 - 104:21; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep., (Vermont)), at 357:1 - 358:22; Henderson Common Exhibit 18 (12/4/2008 Hayashi Dep. (Virginia)), at 27:6 -29:11)

RESPONSE: Disputed to the extent that Ven-A-Care suggests state Medicaid programs had to rely upon prices reported by the compendia for processing the claims at issue in these cases. States did not have to rely upon prices reported by the compendia to adjudicate claims for the drugs at issue. Many states relied upon Federal Upper Limits, established MACs, or utilized other methods to set prices for the drugs at issue. The MAC prices set by the states usually had nothing to do with compendia prices; rather these prices relied upon prices gathered directly from wholesalers or pharmacy providers. (*See* SOAF ¶¶ 49, 96.)

When states did utilize prices published by the compendia (*i.e.* AWPs, WACs), they did so with full knowledge that those prices were not an accurate reflection of acquisition costs. (*See* SOAF ¶ 61, 80.)

60. State Medicaid programs relied on published average wholesale prices (AWPs) and, in some cases, published wholesale acquisition costs (WACs) to estimate acquisition costs and process claims for reimbursement. It would not have been possible for States to process Medicaid claims without relying on AWPs and WACs published by the compendia. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), at 43:16 - 44:21, 63:12 - 64:17; Henderson Common Exhibit 20 (12/9/2008 Fine Dep. (Maryland)), at 48:11 - 50:15; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:12 - 345:11, 348:12 - 350:10; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 282:7 - 284:22; Henderson Common Exhibit 22 (10/29/2008 Clifford Dep. (New Hampshire)), at 203:9 - 203:12; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:16; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 43:2 - 44:22; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep.(Vermont)), at 358:1 - 358:22; Henderson Common Exhibit 23 (11/24/08 Hautea-Wimpee Dep. (Washington)), at 137:1 - 138:21)

RESPONSE: Disputed to the extent that Ven-A-Care is suggesting that state Medicaid programs had to (or in fact did) rely upon prices reported by the compendia for processing the claims at issue in these cases. Many states relied upon Federal Upper Limits, established MACs, or utilized other methods to set prices for the drugs at issue. The MAC prices set by the states usually had nothing to do with compendia prices; rather these prices relied upon prices gathered directly from wholesalers or pharmacy providers. (*See* SOAF ¶ 49, 96.) When states did utilize prices published by the compendia (*i.e.* AWPs, WACs), they did so with full knowledge that those prices were not an accurate reflection of acquisition costs. (*See* SOAF ¶ 61, 80.) Several state Medicaid agencies were able to obtain actual acquisition cost information from pharmacies and utilize the data in setting reimbursement rates. (*Id.* at 49, 52.)

61. State Medicaid officials never told manufacturers that they understood or approved of manufacturers reporting inflated AWPs. (*See, e.g.*, Lavine Decl. at Ex. USAbt-L, K. Gorospe Dep. of Dec. 3, 2008 at 293-295 (California); Ex. USAbt-B, C. Denemark Dep. at 485:1-486:13 (Delaware); Ex. USAbt-E, J. Dubberly Dep. at 76-77 and 355-358 (Georgia); Ex. USAbt-I, R. Stevens Dep. at 322-323 (New Mexico); Ex. USAbt-T, M. Davis Dep. at 63:12-

66:21, 68:8-70:12, and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 141:17-144:10, 147:4-148:12, 155:18-161:13 (Washington)).

RESPONSE: Disputed. Several state Medicaid officials testified that they understood that compendia AWPs were not a reliable source of market prices for generic drugs. (SOAF ¶¶ 61, 80.) These officials testified that they continued to pay more than average acquisition cost in order to further policy goals. (*Id.* ¶¶ 81-96) States allowed a margin in their reimbursement formulae in order to ensure access to care (*id*. ¶ 86), to subsidize inadequate dispensing fees (*id*. ¶ 87), and to encourage providers to dispense generics. (*Id*. ¶ 96.)

62. The firm Myers and Stauffer LC has provided support to the United States' expert witness Mark G. Duggan, Ph.D., in connection with the three cases being jointly litigated by the United States and VAC. As part of that support, Myers and Stauffer gathered information concerning the methodologies used by the Medicaid programs of 48 States and the District of Columbia (the Covered States) to reimburse pharmacy providers for prescription drugs. (Henderson Common Exhibit 24 (Declaration of Kristopher Knerr (Knerr Decl.) ¶¶ 4-12). The information gathered by Myers and Stauffer was described in a series of summaries of drug payment methodologies for each state in the damages reports. The summaries and all supporting information were produced to Abbott in connection with the United States' expert disclosures.

RESPONSE: Admitted, with qualification. Myers & Stauffer also prepared a summary of the drug payment methodology for Ohio; that summary did not accurately summarize Ohio's payment methodology. In addition, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

63. Subsequent to those disclosures, Myers and Stauffer has updated the methodology summaries to reflect information obtained in discovery. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 13-14) All additional materials relied upon by Myers and Stauffer in connection with the updating of the methodology summaries were produced to Abbott on July 24, 2009. (*Id.*, ¶ 13)

RESPONSE: Admitted, with qualification. Abbott does not believe all of the changes and additions to the Myers & Stauffer summaries "reflect information obtained in discovery."

Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

64. In preparing the summaries, Myers and Stauffer relied upon (a) State Plan Amendments obtained from CMS through DOJ; (b) deposition testimony (including testimony from state officials regarding the actual implementation of the payment methodology), deposition exhibits, and documents produced by Covered States pursuant to subpoenas; (c) state statutes, regulations and declarations; (d) annual publications of the National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, from 1990 through 2005/2006; (e) communications with officials of State Medicaid agencies; and (f) policy manuals, provider bulletins, and other similar materials available on state Medicaid agency websites. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 8-10 and 12-13)

RESPONSE: Because Abbott did not work with Myers & Stauffer during their research and preparation of the State methodology summaries, Abbott cannot attest to what information Myers & Stauffer relied upon in preparing their summaries. The Knerr Declaration speaks for itself. Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

65. The methodology summaries are Attachment 1 to Knerr Decl. The information in each summary accurately summarizes the underlying data that was gathered by Myers and Stauffer. (Henderson Common Exhibit 24, (Knerr Decl.), ¶ 5)

RESPONSE: Because Abbott did not work with Myers & Stauffer during their research and preparation of the State methodology summaries, Abbott cannot attest to whether the State methodology summaries accurately summarize all of the underlying data that was gathered by Myers & Stauffer. Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's

Declaration. Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule. (*See also* response to ¶ 76, *infra*.)

66. Currently all Covered States except for Indiana reimburse pharmacy providers for prescription drugs under a "lower of" methodology in which payment is made based, at least in part, on the lower of (a) the State's estimated acquisition cost (EAC) plus a dispensing fee, (b) the pharmacy's usual and customary charge (U&C) (sometimes referred to as the "billed amount"), or (c) the Federal Upper Limit (FUL) established by CMS pursuant to 42 C.F.R. § 447.332; (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 18) Indiana recently eliminated the FUL from its methodology. (*Id.*)

RESPONSE: Abbott disputes the accuracy and materiality of the above statement. Most states currently include a State Maximum Allowable Cost (state MAC) into their payment formula, and many states utilized alternative payment methodologies during some parts of the relevant time period that are not apparent in their state plans. (*See* response to ¶ 59, *infra*) Also, not all of the Covered States currently have a stated methodology that would pay the lower of EAC, U&C, or FUL (*e.g.*, Arkansas). Moreover, the methodologies "currently" used by the states are subject to change. Because the methodologies "currently" utilized by the states are not what is principally at issue, the above statement is not material.

Further responding, the state plan and other material reviewed by Myers & Stauffer do not confirm how the states operated their payment systems in practice. Nor are the state plans and other material reviewed by Myers & Stauffer competent evidence of what the states allegedly "would have paid" on the claims at issue had Abbott reported lower prices for the Erys. Inserting the "corrected" AWPs, WACs, and Direct Prices calculated by Ven-A-Care's expert into existing payment methodologies would also lead to anomalous payment amounts, such as when states applied large discounts off of AWP. Also, Ven-A-Care's theory that the states would have utilized lower prices with their existing payment methodologies – with no changes to their drug payment methodologies – is speculative and inconsistent with the record evidence. For example, extensive record evidence shows that states permitted a margin on ingredient

payments in order to promote the use of generic drugs, subsidize inadequate dispensing fees, and achieve other policy objectives. (*See* SOAF ¶¶ 87-96) Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

67. For the period 1991 to the present, each Covered State used AWP as the primary basis for determining the EAC component of their drug payment methodology, during at least part of that period; 42 of the Covered States used AWP as the primary basis for determining the EAC component of their State's drug payment methodology for the entire time period of 1991 to present. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24a). The remaining Covered States used WAC or a combination of AWP and WAC as the basis for determining the EAC component of their state's drug payment methodology. (*Id.*, ¶ 24b)

RESPONSE: Disputed. The record evidence – including the state plan material, depositions, and other information relied upon by Myers & Stauffer – shows that the states explicitly defined and/or understood that the terms "AWP," "WAC," "Direct Price," "List Price" referred to prices published in the compendia (such as First DataBank) that the states knew generally did not approximate acquisition cost for generic drugs. (*See* SOAF ¶ 61) Furthermore, the record evidence shows that due to FULs and MACs many states relied on other sources of pricing information, such as invoice prices and surveys, rather than AWP for the reimbursement of the Erys. (*Id*. ¶¶ 49, 96.)

Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

68. During the period 1991 to the present, only six Covered States have deviated from the methodology described in the paragraph 29, above: (1) Delaware used Actual Acquisition Cost before May 1, 1997; (2) Michigan used Actual Acquisition Cost, with a limit based on AWP, before September 15, 1995; and (3) Alaska, New York, Arkansas and Massachusetts, each for specific periods of time, did not include EAC in the "lower of" algorithms when the drug was subject to a FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 19)

RESPONSE: Disputed. Paragraph 68 suggests that, from 1991 to the present, all drug claims were, in fact, paid on the lower of (a) the State's estimated acquisition cost (EAC) plus a dispensing fee, (b) the pharmacy's usual and customary charge (U&C), or (c) the Federal Upper Limit established by CMS. Most states included a State Maximum Allowable Cost (state MAC) into their payment formula, and many states utilized alternative payment methodologies during some parts of the relevant time period that are not apparent in their state plans. (*See* SOAF ¶ 49.)

In addition, Hawaii did not always follow its state plan. After 2001, in instances where there was a FUL for a drug that was higher than the state MAC, it was Hawaii's practice to reimburse at the higher FUL. This is contrary to Hawaii's State Plan, which provided for reimbursement at "the lower of" billed charges, the provider's usual and customary charge, estimated acquisition cost, FUL or the State MAC. (4/29/08 Donovan Dep. at 174:6-188:14, Ex. 49; Hawaii State Plan (HHC016-0342), Ex. 178.)

Further responding, the state plan and other material reviewed by Myers & Stauffer do not confirm how the states operated their payment systems in practice.

Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

69. During the period 1991 to the present, 42 of the Covered States have implemented a State Maximum Allowable Cost (SMAC) (sometime under different names) feature. A SMAC is an upper limit established by the State, similar to the FUL, but often determined based on criteria different than the FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 20, 24f) Twenty two of these Covered States have implemented a SMAC program during the entire time period. (*Id.*, ¶ 24f) In all of these Covered States, the SMAC program is incorporated into the "lower of" methodology described above, except that Hawaii does not apply the SMAC if an FUL is in place. (*Id.*, ¶¶ 20, 24e-f)

RESPONSE: Admitted, with the exception of last sentence. To the extent that the last sentence asserts that, from 1991 to the present, the stated methodologies for each of the Covered States provided that these would pay the lower of EAC, U&C, FUL, or SMAC, it is disputed. In addition to the deviations described in paragraph 59, *supra*, many states utilized alternative payment methodologies during some parts of the relevant time period that are not apparent in their state plans. (*See* response to ¶ 59, *supra*; *see also* SOAF ¶ 49) Further responding, the state plan material relied upon by Myers & Stauffer indicates instances where states would not pay the lower of EAC, U&C, FUL, or SMAC, including Arkansas, Massachusetts, Georgia, and Washington.

Further responding, the state plan and other material reviewed by Myers & Stauffer do not confirm how the states operated their payment systems in practice.

Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

70. Twenty-five Covered States add to their "lower of" algorithm, for at least some of the time period, the wholesale pricing information provided in 2000 by the Department of Justice and the National Association of Medicaid Fraud Control Units and published by First DataBank. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 21). Those prices are discussed herein at paragraphs 71 to 74.

RESPONSE: Disputed. The basis cited for this statement (Knerr Decl. ¶ 21) is not consistent with the statement. The Knerr Declaration indicates that "Twentynine (29) states have also used the 'DOJ Price' plus a dispensing fee as part of their reimbursement methodology." (Henderson Common Decl., Ex. 24 ¶ 21.)

Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

71. On or around September 8, 2000, CMS sent Program Memorandum Transmittal AB-00-86 to Medicare Part B carriers, including the DMERCs, providing them with alternative wholesale price information developed jointly by the Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCU). (Abbott Exhibit AP (Thomas Exhibit 83); Roxane Tab 118 (Thomas Exhibit 84); Reid Dec. Exhibit 181 (Thomas Exhibit 85)) The price information covered 32 different drugs, including some of those at issue in the instant cases, compiled mainly from wholesaler catalogs. (*Id.* at 1) (The parties have referred to the alternative AWPs as the DOJ AWPs, although in reality the information consisted simply of prices considered generally and currently paid in the marketplace.) The Transmittal instructed the carriers to consider those alternate wholesale prices in determining Medicare reimbursement amounts. (*Id.*)

RESPONSE: Admitted, but immaterial because this case does not involve Medicare and there were no DOJ AWPs for the Erys at issue.

72. CMS did retract the September 2000 Program Memorandum. (November 17, 2000 Program Memorandum to Carriers and Intermediaries (Roxane Tab 121)(Thomas Exhibit 56)) However, it was not a rejection of the need for pricing information pricing information reflective of what was generally and currently paid in the marketplace. A subsequent HCFA program memorandum made clear that the purpose was to give the General Accounting Office (GAO) time to review Medicare payment policies and to make specific recommendations to the Secretary and Congress as to how to revise drug payment methodologies. (May 3, 2001 Program Memorandum from HCFA to Carriers and Intermediaries (Abbott Exhibit BD) (Thomas Exhibit 86))

RESPONSE: Admitted, but immaterial because this case does not involve Medicare and there were no DOJ AWPs for the Erys at issue.

73. Indeed, the Benefits Improvement and Protection Act of 2000 arose out of efforts by Congress to stop what one representative termed "illegal behavior" and an "outrage." (Henderson Common Exhibit 9 (Medicare Payments for Currently Covered Prescription Drugs: Hearing before the Subcomm. on Health of the House Comm. on Ways and Means, 107th Cong. 7 (2002) (statement of Rep. Stark, Member, House Comm. on Ways and Means))

RESPONSE: Admitted, but immaterial because this case does not involve Medicare.

74. On September 21, 2001, the GAO issued the report as directed by Congress. The GAO report recommended:

> Establish Medicare payment levels for part-B prescription drugs and their delivery and administration that are more closely related to their costs. Payments for drugs should be set at levels that reflect actual market transaction prices and the likely acquisition cost to providers.

(Henderson Common Exhibit 39 (Payments for Covered Outpatient Drugs Exceed Providers' Costs, GAO-01-1118, September 21, 2001))

RESPONSE: Admitted, but immaterial because this case does not involve Medicare.

75. Forty-three Covered States use First DataBank or First DataBank together with Medispan or Red Book as their primary source of information for determining EAC. Of the remaining six Covered States, five use MediSpan as their primary source for determining EAC, and one State uses Red Book for determining EAC. Some Covered States have changed the compendia they use for their prescription pricing, as noted in the respective Myers and Stauffer summaries. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24c)

RESPONSE: Abbott disputes the materiality of the above statement because it provides the purported source of information that states use to determine EAC currently, not during the relevant time period. It is relevant, however, that despite extensive evidence that prices reported by the compendia do not reflect acquisition cost for generic drugs, states continue to use those prices in their payment methodologies.

Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

76. The following paragraphs 36 through 85, concerning the accuracy of State methodology summaries, refer to the summaries in Attachment 1 to the Knerr Decl. The "supporting materials" means the supporting materials referenced in ¶¶ 5 and 12-13 of the Knerr Declaration.

RESPONSE: No response is required because this paragraph does not state material or undisputed facts as required by Local Rule 56.1. *See St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005); *O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006).

With respect to the "State methodology summaries" prepared by the accounting firm of Myers & Stauffer referenced in paragraphs 77-125, *infra*, Abbott disputes that the State methodology summaries represent, as Ven-A-Care contends in paragraphs 77-125 "true and accurate summar[ies] of the features of the prescription drug payment methodolog[ies]" of the states.

The State methodology summaries omit information necessary to be "true and accurate" summaries of the states prescription drug payment methodologies. While the summaries indicate whether the states used "AWP," "WAC," or "Direct Price," and at times indicate where the state obtained that information (usually First DataBank), they fail to describe how the states defined or understood those terms. The record evidence – including the state plan material, depositions, and other information relied upon by Myers & Stauffer – shows that the states generally knew that AWP was an undefined term that did not approximate acquisition cost for generic drugs. (*See* SOAF ¶¶ 54, 61, 80) Because the State methodology summaries fail to provide that information, or describe how states arrived at the EAC levels contained in their state plans, they are not true and accurate summaries of the prescription drug payment methodologies of the states.

In addition, the State methodology summaries are not competent evidence of how states paid for the drug clams at issue; the summaries contain no information on how the claims at issue were actually paid. Many of the claims at issue were reimbursed on the basis of a FUL, MAC, U&C charge, or other basis for reimbursement, yet the summaries provide no information regarding whether, or when, the states applied FULs, MACs, or other bases for reimbursement for the claims at issue. (*See* SOAF ¶¶ 38, 47-48.) Nor do the summaries explain how states arrived at the pricing levels and payment methodologies used for the drug claims at issue.

During the course of its work and discovery, Myers & Stauffer has learned of numerous instances where states did not actually operate their payment systems consistent with their state plans (*see, e.g.*, Henderson Common Decl., Ex. 24, at ¶ 24(e).) As a result, Myers & Stauffer has had to update the summaries to account for additional information. The fact that Myers & Stauffer earlier incorrectly represented the summaries as accurate and complete indicates that they may not be now.

The State methodology summaries are not competent evidence of what the states allegedly "would have paid" on the claims at issue had Abbott reported lower prices for the drugs at issue. While the summaries describe a "lower-of" methodology, the summaries do not confirm that this was how the states operated their payment systems in practice. Moreover, inserting the "corrected" AWPs, WACs, and Direct Prices calculated by Ven-A-Care's expert into existing payment methodologies would also lead to anomalous payment amounts, such as when states applied large discounts off of AWP. Also, Ven-A-Care's theory that the states would have utilized lower prices into their existing payment methodologies – with no changes to their drug payment methodologies – is speculative and inconsistent with the record evidence. For example, extensive record evidence shows that states permitted a margin on ingredient payments

in order to promote the use of generic drugs, subsidize inadequate dispensing fees, and achieve other policy objectives. (*See* SOAF ¶¶ 81-96.) Because these facts are not reflected in the Myers & Stauffer State methodology summaries, the summaries are not true and accurate summaries of the features of the prescription drug payment methodologies of the states.

The State methodology summaries are also vague in numerous instances. For example, the summary for Iowa states:

> Effective 10/1/2003 with NCPDP version 5.1 implementation, all compounds had to be billed on an ingredient by ingredient basis. Prior to 5.1, Iowa Medicaid allowed pharmacies to bill for compounded claims using the NDC of one of the active ingredients, adjusting the price to the full compound price online for those claims $30 and under. Claims that exceeded $30 had to be billed on the Universal Claim Form on an ingredient by ingredient basis.

While this language strongly suggests that compounded drug claims in the state of Iowa were subject to a floor of $30, the impact of this provision on the drug claims at issue is not explained.

The summaries prepared for states which did not always include AWP in their EAC methodologies, such as Florida, Alabama and Rhode Island, do not address whether those states utilized an "AWP proxy" for WAC.

Finally, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

77. The summary for the State of Alabama is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

78. The summary for the State of Alaska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

79. The summary for the State of Arkansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

80. The summary for the State of California is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

81. The summary for the State of Colorado is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

82. The summary for the State of Connecticut is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

83. The summary for the State of Delaware is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

84. The summary for the State of Florida is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

85. The summary for the State of Georgia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

86. The summary for the State of Hawaii is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

87. The summary for the State of Idaho is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

88. The summary for the State of Illinois is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

89. The summary for the State of Indiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

90. The summary for the State of Iowa is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

91. The summary for the State of Kansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

92. The summary for the Commonwealth of Kentucky is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

93. The summary for the State of Louisiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

94. The summary for the State of Maine is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

95. The summary for the State of Maryland is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

96. The summary for the Commonwealth of Massachusetts is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

97. The summary for the State of Michigan is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

98. The summary for the State of Minnesota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

99. The summary for the State of Mississippi is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

100. The summary for the State of Missouri is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

101. The summary for the State of Montana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

102. The summary for the State of Nebraska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

103. The summary for the State of Nevada is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

104. The summary for the State of New Hampshire is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

105. The summary for the State of New Jersey is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

106. The summary for the State of New Mexico is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

107. The summary for the State of New York is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

108. The summary for the State of North Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

109. The summary for the State of North Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

110. The summary for the State of Oklahoma is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

111. The summary for the State of Oregon is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

112. The summary for the Commonwealth of Pennsylvania is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

113. The summary for the State of Rhode Island is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

114. The summary for the State of South Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

115. The summary for the State of South Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

116. The summary for the State of Tennessee is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

117. The summary for the State of Texas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

118. The summary for the State of Utah is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

119. The summary for the State of Vermont is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

120. The summary for the Commonwealth of Virginia is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

121. The summary for the State of Washington is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

122. The summary for the State of West Virginia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

123. The summary for the State of Wisconsin is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

124. The summary for the State of Wyoming is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

125. The summary for the District of Columbia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

RESPONSE: Disputed. *See* response to ¶ 76, *supra*.

126. States request federal Medicaid funds on a quarterly basis. Henderson Common Exhibit 25 (Declaration of Kristin A. Fan (Fan Decl.), ¶ 5) The process generally begins 45 days before the upcoming quarter begins, with each state submitting to CMS a budget of what it projects the state will spend during the upcoming quarter. *Id.*; 42 C.F.R. § 430.30(b). The state Medicaid official provides the information electronically using a Form CMS-37. (*Id.*, ¶ 5) Along with the overall funding request, the state will provide estimates of various types of services, including drug costs. *Id.* Further, the CMS-37 includes a certification that states in part:

> The fiscal year budget estimates only include expenditures under the Medicaid program under title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under title XXI of the Act, that are allowable in accordance with applicable implementing Federal, state, and local statutes, regulations, policies, and the state plan approved by the Secretary and in effect during the fiscal year under title XIX of the Act for the Medicaid program, and as applicable, under title XXI of the Act for the SCHIP. The budget estimates are based upon the most reliable information available to the state.

Id.

RESPONSE: Disputed. Abbott disputes that states provide estimates of "drug costs," as this alleged fact is not supported by Ven-A-Care's proffered evidence. Moreover, Abbott objects to Ven-A-Care's reliance on the Fan Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to the Fan Declaration. Further responding, Abbott states that the Fan Declaration is hearsay and violates the Best Evidence Rule.

127. A state's budget estimate for a given quarter is normally based on the state's Medicaid expenditures in prior quarters. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 6) Therefore, if drug expenditures in prior quarters are improperly inflated, this would likely cause absent an adjustment, the budget estimate for a subsequent quarter to be inflated. *Id.*

RESPONSE: Admitted, with qualification. The Form CMS-37 includes a field for "Prescribed Drugs," but does not break down a state's budget estimate into drug ingredient costs or dispensing fees. Nor does the Form CMS-37 break down a state's budget estimate for individual drugs. The federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant

flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* 42 U.S.C. § 1396a(a)(30)(A).

Further responding, Ven-A-Care has provided no evidence that any state's budget estimates for any quarter were "improperly inflated" or in any way inconsistent with the federal, state, and local statutes, regulations, policies, and the state plans approved by HHS. Moreover, Abbott objects to Ven-A-Care's reliance on the Fan Declaration, which was submitted after the close of discovery, to the extent it contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to the Fan Declaration. Further responding, Abbott states that the Fan Declaration is hearsay and violates the Best Evidence Rule.

128. The CMS 37 form is sent to the appropriate regional CMS office. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 7); 42 C.F.R. § 430.30(b), (d). Upon receipt, regional office staff will review the form and make recommendations to the CMS central office as to whether the state funding request should be approved, approved with adjustments, or denied. 42 C.F.R. § 430.30(d); *Id.*, ¶ 7) The CMS central office reviews the regional analyst's recommendations. (*Id.*, ¶ 7) In deciding what funding level to approve for the following quarter, the CMS central office "considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant." (*Id.*; 42 C.F.R. § 430.30(d)(2)) In determining whether any adjustments should be made under subsection (d)(2) of the regulation, the central office examines any expenditures from previous quarters. (*Id.*, ¶ 7; 42 C.F.R. § 430.30(d)(2)) Once the funding request is approved, the state can draw down the federal monies on a federal letter of credit for the allotted amount as costs are incurred. (*Id.*, ¶ 7) The State draws down federal funds through a commercial bank and the Federal Reserve System. *Id.*

RESPONSE: Admitted.

129. Section 430.30(d)(3), 42 C.F.R., provides that the grant award "authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements." It is CMS's position that the state's quarterly federal Medicaid award is only to be used to reimburse Medicaid providers for actual payments. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 8) In practice, a state draws down federal funds as actual payments are made by the State to Medicaid providers, including pharmacies and physicians seeking payment for drugs. *Id.* Thus, if a state overpays providers because of false provider claims, the state's draw-down on the letter of credit for the federal share will be affected, unless an adjustment is made. (*Id.*, ¶ 8)

RESPONSE: Admitted, with qualification. Ven-A-Care has provided no evidence that any state "overpa[id] providers because of false provider claims" attributable to the drugs at issue, or that any federal grant payments were made that were in any way inconsistent with the federal, state, and local statutes, regulations, policies, and the state plans approved by HHS. The federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* 42 U.S.C. § 1396a(a)(30)(A). Moreover, Abbott objects to Ven-A-Care's reliance on the Fan Declaration, which was submitted after the close of discovery, to the extent it contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to the Fan Declaration. Further responding, Abbott states that the Fan Declaration is hearsay and violates the Best Evidence Rule.

130. After each calendar quarter, the state must submit to CMS a reconciliation of its actual Medicaid expenditures against the monetary advance made on the basis of the Form 37. 42 C.F.R. § 430.30(c). The state electronically submits this information using a Form CMS-64. A State submitting the Form CMS 64 makes a certification that includes the following:

I certify that:

1. I am the executive officer of the state agency or his/her designate authorized by the state to submit this form.

2. This report only includes expenditures under the Medicaid program under Title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under Title XIX of the Quarter Ended indicated above under Title XXI of the Act.

3. The expenditures included in this report are based on the state's accounting of actual recorded expenditures, and are not based on estimates.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 9)

RESPONSE: Admitted.

131. The CMS web site provides an explanation of the Form CMS-64. Centers for Medicare and Medicaid Services, Medicaid Budget and Expenditure System (Medicaid Quarterly Expense Report), available at http://www.cms.hhs.gov/MedicaidBudgetExpendSystem/02_CMS64.asp. It states in part:

> The amounts reported on Form CMS-64 and its attachments must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the claim is filed. Form CMS-64 is a statement of expenditures for which states are entitled to Federal reimbursement under Title XIX and which reconciles the monetary advance made on the basis of Form CMS-37 filed previously for the same quarter. Consequently, the amount claimed on the Form CMS-64 is a summary of expenditures derived from source documents such as invoices, cost reports and eligibility records.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 10)

RESPONSE: Admitted.

132. The information in the Form CMS-64 is a source of information used in adjusting future Form-37 funding requests. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 11; 42 C.F.R. § 430.30(d)(2)) If CMS believes that it has overpaid a state based on its review of the Form-64, or otherwise, CMS may adjust future authorizations to offset the overpayment or seek to recover the amount overpaid. (42. U.S.C. § 1396b(d)(5); *Id.*, ¶ 11) While federal funding is made available prospectively to state Medicaid programs, the quarterly funding level for a state's Medicaid program is directly determined based on the state's actual, quarterly Medicaid expenditures. (*Id.*, ¶ 11)

RESPONSE: Admitted, with qualification. The Form CMS-64 includes a field for "Prescribed Drugs," but does not break down a state's expenditures into drug ingredient costs or dispensing fees. Nor does the Form CMS-64 break down a state's expenditures for individual drugs. The federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* 42 U.S.C. § 1396a(a)(30)(A)) Moreover, Abbott objects to Ven-A-Care's reliance on the Fan Declaration, which was submitted after the close of discovery, to the extent it contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to the Fan Declaration. Further responding, Abbott states that the Fan Declaration is hearsay and violates the Best Evidence Rule.

Further responding, Ven-A-Care has provided no evidence that any state's expenditures for any quarter were inconsistent with the federal, state, and local statutes, regulations, policies, and the state plans approved by HHS.

133. Many third-party payors, including state, federal government and private health plans, use database products from national drug pricing compendia in determining their payment levels for drugs eligible for payment under their benefit plans. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 25-84;) *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp. 2d 172, 178 (D. Mass. 2003)).

RESPONSE: Disputed. Abbott disputes the statement as unsupported by Ven-A-Care's proffered evidence. Abbott also states that although the information provided by the pricing

compendia may have been a part of the payment formulas used by some third party payors, it was universally understood that the published prices did not represent actual acquisition costs paid by providers. The documents and data produced by Abbott and by the pricing compendia are the best evidence of their content. Moreover, Abbott objects to Ven-A-Care's reliance on Knerr's Declaration, which was submitted after the close of discovery, because it contradicts pre-existing facts in the record, and because Abbott has not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Abbott states that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

134. Plaintiff lists the AWPs published by FDB for Abbott's Ery products as contained in the exhibits attached to the Declaration of Ian Dew filed in Support of Plaintiffs Motion for Partial Summary Judgment. Abbott reported so-called "list prices" for these products to FDB, knowing and relying on FDB to make a known mathematical calculation to the list prices to determine an AWP for publication. Abbott knew that published AWPs were based on 125% of Abbott's reported WACs. Beth Garvin-Senger Tr. at 46-47 (Thomas Exhibit 1).

RESPONSE: Disputed. While Abbott PPD submitted WACs and list prices for the Ery drugs, the compendia actually calculated the AWPs for them. (30(b)(6) Fiske Dep. at 143:23-144:1, 175:16-23, Ex. 2; 1/15/09 Lehn Dep. at 63:14-21, Ex. 3.) Abbott informed Red Book on many occasions that it never intended to control the AWP published by the pricing compendia. (*See* Gerzel Ex. 10 ("Abbott does not control how Red Book does its business nor does Abbott provide AWP or a calculated markup to establish an AWP. Consequently, Abbott concluded that there was no need to respond to Ms. Voeck's April 2003 letter. Abbott trusts that Red Book will continue to conduct its business as it sees fit."), Ex. 23.) *See also*, 2/20/09 Gerzel Dep. at 127:5-129:14, Ex. 10; 30(b)(6) Fiske Dep. at 142:18-144:12, Ex. 2.) Abbott's PPD employees testified that they believed that they reported the prices that the pricing compendia wanted and in accordance with Abbott's use of the terms (30(b)(6) Fiske Dep. at 166:24-167:7; 195:7-14; 197:2-6, Ex. 2; 2/20/09 Gerzel Dep. at 44:24-45:13, Ex. 10.)

135. A corporate designee for one of the compendia publishers, Red Book, testified that the manufacturers controlled the prices published in the Red Book. Kristin Minne testified that AWP was a required Red Book field until early 2003. (Henderson Common Exhibit 26 (11/18/08 Minne Dep.), at 158:9 -159:1) AWPs were provided to Red Book by the Defendants, and those manufacturer-supplied AWPs were then entered into the pricing database. (*Id.*, 158:9 - 159:1) Annually, Red Book sends a Product Listing Verification (PLV) form to each manufacturer. (*Id.*, 84:11-87:1) The PLV includes a print out of the manufacturer's drugs as they are currently listed by Red Book, and it requests that the manufacturer verify and confirm that their products' pricing information is accurate. (*Id.*, 95:6 - 96:14)

RESPONSE: Disputed. Abbott PPD did not control and report AWPs to the Red Book. While Abbott PPD submitted WACs and list prices for the Ery drugs, the compendia actually calculated the AWPs for them. (30(b)(6) Fiske Dep. at 143:23-144:1, 175:16-23, Ex. 2; 1/15/09 Lehn Dep. at 63:14-21, Ex. 3.) Although Abbott admits that Red Book sent PLVs to Abbott, Abbott PPD refused to verify AWPs. Abbott informed Red Book on many occasions that it never intended to control the AWP published by the pricing compendia. (*See* Gerzel Ex. 10 ("Abbott does not control how Red Book does its business nor does Abbott provide AWP or a calculated markup to establish an AWP. Consequently, Abbott concluded that there was no need to respond to Ms. Voeck's April 2003 letter. Abbott trusts that Red Book will continue to conduct its business as it sees fit."), Ex. 23.) (*See also*, 2/20/09 Gerzel Dep. at 127:5-129:14, Ex. 10; 30(b)(6) Fiske Dep. at 142:18-144:12, Ex. 2.)

136. As of early 2003, Red Book implemented a new AWP Policy, in which manufacturers were no longer required to report their AWPs. If they chose not to report an AWP, Red Book would calculate and publish an AWP based on a percentage markup from the manufacturer's reported WAC or DP. Manufacturers were notified of what this standard mark-up formula would be. (Henderson Common Exhibit 26 (11/18/08 Minne Dep.), at 159:11 - 160:1) Manufacturers choosing to report only a WAC or DP provided guidance to Red Book on how to calculate an AWP for their product. (*Id.*, 171:2 - 171:18). Abbott PPD continued to allow AWPs to be published for PPD drugs, including the Erys (April Gerzel Tr. 2/20/09 at 52-53 (Thomas Exhibit 35)).

RESPONSE: Disputed. Abbott PPD told Red Book that it, not Abbott, calculated AWPs, and Abbott PPD refused to help Red Book. (*See* Gerzel Ex. 10 ("Abbott does not control how Red Book does its business nor does Abbott provide AWP or a calculated markup to establish an

AWP. Consequently, Abbott concluded that there was no need to respond to Ms. Voeck's April 2003 letter. Abbott trusts that Red Book will continue to conduct its business as it sees fit."), Ex. 23.) *See also*, 2/20/09 Gerzel Dep. at 127:5-129:14, Ex. 10; 30(b)(6) Fiske Dep. at 142:18-144:12, Ex. 2.) Abbott could not control whether Red Book published AWPs.

137. On October 3, 2002, the Office of Inspector General for the Department of Health and Human Services published "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 67 Fed. Reg. 62057-62067 (Oct. 3, 2002). The Draft Guidance identified "major risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . ." 67 Fed. Reg. at 62060. The Draft Guidance further stated:

> Many Federal and state health care programs establish reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act, if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately.

67 Fed. Reg. at 62060.

RESPONSE: Undisputed that the OIG issued the cited draft guidance in the Federal Register in October 2002 and that the Federal Register contains the excerpted language. However, Abbott objects as the above language is incomplete. The draft guidelines contained the following disclaimers: (1) "The contents of this guidance should not be viewed as mandatory . . . . The document is intended to present voluntary guidance to the industry and not represent binding standards for pharmaceutical manufacturers," (67 Fed. Reg. 62058 (Oct. 3, 2002)), and (2) "This guide is not a compliance program" (*id*). Because the draft guidelines did not impose any binding obligations on Abbott, this passage is immaterial to any party's motion for summary

judgment. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch &Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005). Finally, Abbott states that it did not submit any false, fraudulent, or misleading information and that Medicaid payments for Ery were not based on AWPs or Abbott's reported prices. (SOAF ¶ 38-39, 48-50.)

138. On May 5, 2003, the Office of Inspector General for the Department of Health and Human Services published final "OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 68 Fed. Reg. 23731-23743 (May 5, 2003). The Guidance identified "major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . ." 68 Fed. Reg. at 23732. The Guidance identified "Specific Risk Areas" for pharmaceutical manufacturers, including "[i]ntegrity of data used by state and Federal governments to establish payment amounts." 68 Fed. Reg. at 23733.

The Guidance further stated:

> Many Federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately."

Id.

RESPONSE: Undisputed that the OIG issued the cited guidance in the Federal Register in May 2003 and that the Federal Register contains the excerpted language. However, Abbott objects as the above language is incomplete. The guidelines explicitly disclaimed that: (1) "This guide is not a compliance program." (68 Fed. Reg. 23731 (May 5, 2003)), and (2) "This guidance does not create any new law or legal obligations, and the discussions that follow are not intended to

present detailed or comprehensive summaries of lawful and unlawful activity" (*id*. at 23733). Because these guidelines did not impose any binding obligations on Abbott, this passage is immaterial to any party's motion for summary judgment. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005). Abbott also notes that the guidelines specifically did not define AWP.

139. Pursuant to the Medicaid Drug Rebate Statute (Rebate Statute), pharmaceutical manufacturers (including Abbott) are required to enter into a national Medicaid Rebate Agreement with the CMS. 42 U.S.C. § 1396r-8(a)(1). Once a manufacturer enters a rebate agreement with CMS, state Medicaid programs are required, with certain limited exceptions, to reimburse providers for that manufacturer's drugs. 42 U.S.C. § 1396r-8(d).

RESPONSE: Ven-A-Care does not state undisputed or material facts in paragraph 139. Rather, Ven-A-Care provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 139 could be read to state undisputed or material facts, they are disputed. 42 U.S.C. § 1396r-8(a)(1) does not require all pharmaceutical manufacturers to enter into a Medicaid Rebate Agreement, but rather requires a pharmaceutical manufacturer to enter into a Medicaid Rebate Agreement as a precondition to that manufacturer's drugs being reimbursed by state Medicaid programs. 42 U.S.C. § 1396r-8(d) permits state Medicaid programs to place further restrictions on drug coverage, such as formularies, prior authorization programs, and quantity restrictions.

140. Pursuant to the Rebate Statute, drug manufacturers (including Abbott) are required to calculate and submit AMPs to CMS on at least a quarterly basis. 42 U.S.C. § 1396r-8(b)(3) and (k)(1).

RESPONSE: Ven-A-Care does not state undisputed or material facts in paragraph 140. Rather, Ven-A-Care provides a legal conclusion; therefore, no response should be required. *See O'Brien*

v. Town of Agawam, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 140 could be read to state undisputed or material facts, they are not disputed.

141. CMS administers the Rebate Statute in part by using a manufacturer's AMP information and drug utilization information submitted by States to calculate a "Unit Rebate Amount" (URA). 42 U.S.C. § 1396r-8(b)(2)(A). The URA is the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

RESPONSE: Disputed. The Unit Rebate Amount ("URA") is calculated solely from information provided by manufacturers. For instance, for non-innovator multiple-source drugs, the URA is 11 percent of the average manufacturer price ("AMP") as reported by the manufacturer. (*See* 42 U.S.C. § 1396r-8(b)(3)) CMS does not rely on any information submitted by states to calculate URAs. Abbott does not dispute that states are supposed to submit utilization information.

142. The Rebate Statute requires that AMPs provided to CMS be kept confidential and not be disclosed by CMS except for the purpose of carrying out the purposes of the rebate program. 42 U.S.C. § 1396r-8(b)(3)(D). Abbott PPD employees understood that the AMPs would be kept confidential by the government. Beth Garvin-Senger Tr. 12/17/08 at 118:8 to 118:12 (Thomas Exhibit 1).

RESPONSE: Ven-A-Care does not state undisputed or material facts in paragraph 142. Rather, Ven-A-Care provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 142 could be read to state undisputed or material facts, they are disputed. 42 U.S.C. § 1396r-8(b)(3)(D) does not contain an unconditional requirement that CMS keep AMPs confidential. Nor does it unconditionally limit the use of AMPs to the Medicaid rebate program. During most of the time period relevant to this action, 42 U.S.C. § 1396r-8(b)(3)(D) provided in relevant part:

> Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph … is confidential and shall not be disclosed by the Secretary… or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices

> charged for drugs by such manufacturer or wholesaler, except – (i) as the Secretary determines to be necessary to carry out this section…, (ii) to permit the Comptroller General to review the information provided, and (iii) to permit the Director of the Congressional Budget Office to review the information provided.

(42 U.S.C. § 1396r-8(b)(3)(D). There is nothing contained in the text of this subsection that would prohibit CMS from using AMPs internally for purposes other than the Medicaid rebate program, or from publicly disclosing AMPs, or information derived from AMPs, in a manner that does not identify a particular manufacturer or wholesaler, or prices paid by a particular manufacturer or wholesaler. The section contemplates providing AMPs directly to state Medicaid agencies, as the text of the section expressly extends the disclosure limitations to state agencies and their contractors. Indeed, while CMS refused to provide AMPs to state agencies, CMS has informed states since at least 1997 that they were free to gather AMP information directly from manufacturers for their own uses. (June 20, 1997 DHHS letter to Medi-Cal regarding AMP, Ex. 179.) Texas, California, Maine, and Vermont all require drug manufacturers to report AMPs directly to their respective Medicaid programs. (*See* 1 Tex. Admin. Code § 354.1927; Me. Rev. Stat. Ann. Tit. 22 § 2698-B; Vt. Stat. Ann. Tit. 33 § 2010(a).) Furthermore, Abbott disputes paragraph 142 to the extent it mischaracterizes the testimony of Ms. Senger. Ms. Senger did not have knowledge of any legal restrictions on the government's ability to share the AMPs which Abbott submitted. (12/7/08 Senger Dep. at 118:21-119:6, Ex. 5.)

143. The specific rebate agreements entered into between CMS and Abbott states as follows:

> Pursuant to Section 1927(b)(3)(D) of the [Social Security] Act and this Agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices changed by the Manufacturer, except as necessary by the Secretary to carry out provisions of [the Rebate Statute].

(Roxane SOF, Tab 143, p. 9 (Thomas Exhibit 89); Reid Decl., Exhibit 34 (Thomas Exhibit 90))

RESPONSE: Admitted.

144. In a 1995 proposed rulemaking published at 60 Fed. Reg. 48442 (1995), the Department of Health and Human Services stated as follows concerning AMP information:

> C. Confidentiality of Manufacturer Price Information
>
> Comment: Many of the commenters believed that States should not have access to manufacturers' price information, including unit rebate amounts, since HCFA has access to this information. The commenters stated that the risk of disclosure and use of information for other purposes is too great.
>
> Response: We have agreed not to disclose AMP and best price to States but maintain that the statute contemplates the disclosure of manufacturer pricing data to States. Section 1927(b)(3)(D) of the Act provides that information concerning drug prices must not be disclosed by "the Secretary or a State agency (or contractor therewith)." By including States within the confidentiality provisions, we believe that the Congress intended that States have the right to access of sufficient pricing information to calculate their rebates as required by the statute. The unit rebate amount, which provides the rebate due per tablet, etc., and which is the end result of the manufacturer's calculation, is, in our opinion, the minimum amount of information States need to accomplish this. At the same time, the statute protects the manufacturer's pricing data from disclosure. In accordance with section 1927(b)(3)(D) of the Act, information disclosed by manufacturers in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act, 5 U.S.C. 552) must not be disclosed by HCFA, the State agency, or its contractors in a form that reveals the manufacturer, except as necessary for the Secretary of HHS to carry out the provisions of section 1927 and for the Comptroller General or the Director of the Congressional Budget Office to review the information provided.

RESPONSE: Abbott does not dispute that paragraph 144 accurately quotes 60 Fed. Reg. 48442 (1995). Abbott disputes that the quoted portions of 60 Fed. Reg. 48442 (1995) constitute a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its response to paragraph 144 above. Abbott further states that, in a 2001 report, the OIG discussed the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and CMS's interpretation of them:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

(*See* OEI-05-99-00611 Medicaid HIV/AIDS Drugs Cost Containment, at 22, Ex. 180.) Ann Maxwell, the Government's 30(b)(6) designee in the DOJ case, and a regional inspector general at the OIG, testified that this paragraph "accurately discusses the confidentiality provisions surrounding AMP." (6/10/09 Maxwell Dep. at 129:1-131:3, Ex. 181.)

145. In an exchange of letters in October 1991 and May 1992 relating to the State of Hawaii's implementation of the Medicaid Rebate statute, HCFA requested, and Hawaii gave assurances that "the State will keep the unit rebate amount confidential and will not disclose it for purposes other than rebate invoicing and verification." (Henderson Common Exhibits 27 and 28)

RESPONSE: Abbott does not dispute that paragraph 145 accurately characterizes Henderson Common Exhibits 27 and 28. Abbott disputes that the quoted portion of Henderson Common Exhibit 28 is based upon a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its responses to paragraphs 142 and 144 above.

146. On or about April 22, 2004, CMS approved a New Hampshire State Plan Amendment allowing the State to enter into the Michigan Multi-State Pooling Supplemental

Drug Rebate Agreement. The SPA included the statement, "[t]he unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act." (Henderson Common Exhibit 29)

RESPONSE: Abbott does not dispute that CMS approved the New Hampshire State Plan Amendment as described in paragraph 146 and does not dispute Henderson Common Exhibit 29 contains the language quoted in paragraph 146. Abbott disputes that the quoted language or the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) would prohibit CMS or New Hampshire from disclosing URAs or information derived from URAs in a manner that did not identify a specific manufacturer or wholesaler or prices paid by a specific manufacturer or wholesaler, or would otherwise prohibit CMS or New Hampshire from using URAs internally for purposes other the Medicaid rebate program. Abbott incorporates herein its responses to paragraphs 142 and 144 above.

147. In a September 2001 "Medicaid Drug Rebate Operational Training Guide" prepared by CMS's Center for Medicaid and State Operations, the agency stated that AMPs:

> are generally subject to both privacy and trade secret restrictions and are not released by CMS and must not be released by states. The pricing data CMS receives is held in the strictest confidence, and must not be released by states. The pricing data CMS receives is held in the strictest confidence and maintained only on CMS's master files. CMS sends URAs to states, but actual pricing data goes no farther than CMS.

(Roxane SOF, Tab 142A, at D2) (Thomas Exhibit 91)

RESPONSE: Abbott does not dispute that paragraph 106 accurately quotes from Tab 142A of Roxane's Statement of Facts. Abbott disputes that the quoted portion of Tab 142A of Roxane's Statement of Facts constitutes a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its responses to paragraphs 142 and 144 above.

148. In a letter to the State of Texas dated May 3, 2004, CMS stated:

> You ask for confirmation that State Medicaid programs may not use the rebate information, including the Unit Rebate Amount (URA) and Reconciliation of State Invoice (ROSI) reports, to calculate an estimated acquisition cost (EAC) for reimbursement. You are correct. In light of the confidentiality provisions of Section 1927(b)(3)(D) of the Social Security Act, drug pricing information disclosed by manufacturers pursuant to the drug rebate provisions is confidential and shall not be disclosed by either the Secretary or the State.

(Henderson Common Exhibit 31)

RESPONSE: Abbott does not dispute that paragraph 148 accurately quotes from Henderson Common Exhibit 31. Abbott disputes that the quoted portion of Henderson Common Exhibit 31 constitutes a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein its responses to paragraphs 142 and 144 above. Abbott further states that, in 2001, the OIG recommended that CMS use AMPs to create "estimated acquisition costs" ("EACs") to be used to calculate Medicaid reimbursement or, in the alternative, provide AMPs directly to state Medicaid programs so that the state Medicaid programs could use AMPs to calculate EACs. (*See* OEI-05-99-00611 Medicaid HIV/AIDS Drugs Cost Containment, at 22, Ex. 180.) The OIG further stated that using AMPs in this manner would not be inconsistent with the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D). (*See id*. at 22.) Furthermore, regardless of CMS's position regarding the use of AMPs as a reimbursement basis, Texas requires manufacturers to report AMPs to it directly. (See response to ¶ 142, *supra*.)

149. In a statement submitted to the Subcommittee on Health Care of the Senate Finance Committee on or about March 14, 2002, CMS Administrator Thomas Scully stated, "We collect AMP data for Medicaid on one side of my agency. . . . But by statute we're not allowed to share that with the Medicare side of the agency. It's proprietary data just for the purpose of the Medicaid program. . . . . the law that created it prohibited us from using AMP for Medicare. . . . . AMP provides a pretty good source of data, but by statute it is limited to use for the Medicaid program and the Medicare side of my agency doesn't have access to it by law." "Reimbursement and Access to Prescription Drugs Under Medicare Part B," 107th Cong. 16, Hearing Before the Subcomm. on Health Care of the S. Finance Comm. (March 14, 2002) (statement of Thomas A. Scully), 2002 WL 399357 at *18-19.

RESPONSE: Abbott does not dispute that paragraph 149 accurately quotes the referenced Congressional testimony. Abbott disputes that the quoted portion of the testimony constitutes a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its responses to paragraphs 142 and 144 above. Abbott further states that, in his testimony in this action, Mr. Scully acknowledged that one could easily compare AMPs to AWPs and calculate spreads between the two:

> Q. Okay. So, CMS employees, to nail this down, could sit down and take a look at the AMP for Albuterol, and compare that to the AWP for Albuterol, and calculate precisely the spread between those two points; right?
>
> MR. NEAL: I'll object to the form.
>
> MR. RIKLIN: Objection to form.
>
> A. I believe that's true, yes.
>
> Q. And that data existed within CMS Medicaid during the entire time that Dey's products were reimbursed under Medicaid; right?
>
> MR. NEAL: Objection as to form.
>
> A. I don't know what year we started collecting AMP, but whenever they started collecting AMP, yes.

(7/13/07 Scully Dep. at 619:4-18, Ex. 17.)

150. Larry Reed, Technical Director in the Division of Pharmacy, CMS, testified regarding AMP information submitted by manufacturers, stating, "The information that we would get from the manufacturers would not be part of the reimbursement system. The information that we get from the manufacturers would be part of the rebate program, the AMP data, the best price data." (Henderson Common Exhibit 32 (10/2/08 Reed Dep.), at 1094:4-9)

RESPONSE: Abbott does not dispute that paragraph 150 accurately quotes Mr. Reed's deposition testimony. Abbott disputes that the quoted portion of the testimony is based upon or reflects a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its responses to paragraphs 142 and 144 above.

151. Responsible officials at CMS testified that understood AMPs were confidential, and could only be used for purposes of the Rebate Program. *See, e.g.* (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 282:20 - 283:4; Henderson Common Exhibit 34 (9/27/2007 Reed Dep.), at 352:14 - 353:11; Henderson Common Exhibit 35 (6/21/2007 Vladeck Dep.), at 457:19 - 460:20, 464:7 - 464:19, 584:21 - 586:4; Henderson Common Exhibit 36 (2/27/2007 Duzor Dep.), at 368:14 - 369:10)

RESPONSE: Abbott does not dispute that paragraph 110 accurately refers to the referenced testimony. Abbott disputes that the cited testimony constitutes a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its responses to paragraphs 142, 144, and 148 above. Abbott further states that, regardless of the confidentiality provisions of 42 U.S.C. § 1396r- 8(b)(3)(D), state Medicaid programs had access to AMPs and could compare them to their reimbursement payments. For instance, Bruce Vladeck, the Administrator of HCFA from May 1993 to September 1997, testified:

> Q: So as far as you know, people within HCFA shared AMP data with state Medicaid agencies?
>
> A: That was my understanding.
>
> * * *
>
> Q: So it was entirely possible -- it was entirely possible for the heads of a state Medicaid agency to look at the AMP data on AMP prices and at the same time look at data as to what they were reimbursing for those drugs. That was entirely possible. Right?
>
> * * *
>
> A: It's -- I don't know any reason why it wouldn't be possible.

(6/21/07 Vladeck Dep. at 461:12-15, 463:19-464:06, Ex. 182.) Likewise, Thomas Scully, the Administrator of CMS from May 2001 to December 2003, testified:

> Q: Did you ever tell any state that they should calculate their reimbursement methodology for Medicaid taking into account AMP data?
>
> A: No.
>
> Q: Why not?

> A: States have AMP data, and they have their own political calculations, and reasons for paying the rates they pay.

(7/13/07 Scully Dep. at 627:13-20, Ex. 17.) Deirdre Duzor, the CMS Director of the Pharmacy Division for the Medicaid program, testified that it would be relatively simple to derive the AMP from a URA for a generic drug:

> Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?
>
> * * *
>
> A: Yes. The AMPs have been fairly transparent for generic drugs.

(1/8/09 Duzor Dep. at 679:12-17, Ex. 183.)

152. AMPs were not utilized in the calculation of Federal Upper Limits, as AMPs were not listed in "published compendia." 42 C.F.R. § 447.332(a)(1)(ii); Henderson Common Exhibit 40 (Declaration of Susan Gaston), ¶ 6 [Exhibits omitted]. Persons responsible for setting FULs at CMS did not use AMPs, as AMPS are not listed in "published compendia." *Id.*; Henderson Common Exhibit 37 (3/19/2008 Gaston Dep.), at 528:4 - 529:1)

RESPONSE: Abbott does not dispute that AMPs were not utilized in the calculation of Federal Upper Limits ("FULs"). To the extent Ven-A-Care asserts that AMPs could not be used to calculate FULs because of the provisions of 42 C.F.R. § 447.332(a)(1)(ii), Ven-A-Care does not state undisputed or material facts. Rather, Ven-A-Care provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that this assertion could be read to state undisputed or material facts, they are disputed. Abbott states that, regardless of the provisions of 42 C.F.R. § 447.332(a)(1)(ii), there is nothing that would legally prohibit CMS from incorporating AMPs into Medicaid reimbursement methodologies or allowing states to do the same. Abbott incorporates herein its responses to paragraphs 142, 144, and 147 above.

153. AMPs were on occasion provided to HHS, Office of the Inspector General, in furtherance of the OIG's mission to conduct audits and investigations, and to prevent and detect waste, fraud and abuse in the agency's programs and operations. 5 U.S.C. app. 3 §§ 2, 4, 8G

(1988). However, responsible officials at OIG testified that they understood AMPs were confidential. (Henderson Common Exhibit 38 (2/6/2008 Vito Dep.), at 1196:10 - 1196:19) OIG and other governmental reports regularly referred to AMPs as confidential.

RESPONSE: Abbott does not dispute that AMPs were provided to the United States Department of Health and Human Services, Office of Inspector General. Abbott does not dispute that paragraph 153 correctly describes the cited deposition testimony and documents. Abbott disputes that the cited testimony and documents are based upon or reflect a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its responses to paragraphs 142 and 144 above.

154. CMS did not instruct states to use AMPs for reimbursement. (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 281:16-22)

RESPONSE: Admitted.

155. State Medicaid officials have testified that they understood that AMPs were confidential, and that they could not use AMP information in setting reimbursement rates. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), p. 70:5 - 72:22; Henderson Common Exhibit 43 (12/3/2008 Gorospe Dep. (California)), at 283:8 - 284:21; Henderson Common Exhibit 11 (12/15/2008 Dubberly Dep. (Georgia)), at 83:20 52 - 86:18; Henderson Common Exhibit 12 (11/18/2008 Parker Dep. (Illinois)), at 72:2 - 74:8; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 287:1 - 293:17; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 77:1 - 77:16, 102:18 - 103:19; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 112:8 -113:10; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep. (Vermont)), at 373:1 - 373:20)

RESPONSE: Abbott does not dispute that paragraph 155 accurately describes the cited testimony. Abbott disputes that the cited testimony is based upon or reflects a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporates herein its responses to paragraphs 142, 144, and 147 above. Furthermore, regardless of whether state Medicaid officials believe that they can use AMPs to calculate reimbursement payments, states are free to gather AMPs directly from manufacturers. (*See* response to ¶ 142, *supra*.) Texas, California, Maine, and Vermont require drug manufacturers to report AMPs directly to their respective state Medicaid programs. (*See id*.)

156. In a 2001 report, the OIG discussed the confidentiality of the AMPs as follows:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

Reid Dec. Exhibit 38 at 22) (Thomas Exhibit 92)

RESPONSE: Admitted

Dated: November 2, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara A. Fumerton an attorney, hereby certify that I caused a true and correct copy of the foregoing Abbott Laboratories Inc.'s Response to Ven-A-Care's Rule 56.1 Statement to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 2nd day of November, 2009.

/s/ Tara A. Fumerton
Tara A. Fumerton